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# ASSESSMENT OF ENVIRONMENTAL RISK STANDARDS IN THE UK

***Final Report to Her Majesty's Inspectorate of Pollution (HMIP)***

DoE 4116
APRIL 1996

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# ASSESSMENT OF ENVIRONMENTAL RISK STANDARDS IN THE UK

Final Report to Her Majesty's Inspectorate of Pollution

Report No: DoE 4116

April 1996

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CONTENTS Page

Page

## APPENDICES



## LIST OF TABLES

Page

## LIST OF FIGURES

# EXECUTIVE SUMMARY

HMIP uses environmental Standards in BPEO assessments as comparator values against which concentrations of substances in different environmental media resulting from releases, can be compared and their relative significance assessed. However, Standards derive from a variety of sources and differences in their basis, their derivation and the extent to which risk is assessed in each procedure makes their use in identification of the BPEO complicated and potentially unreliable. This report aims to address these issues by reviewing the "state-of-the-art" in Standard setting and identifying options for the development of a more consistent approach. Analysis indicates that it is not possible to retrospectively evaluate the degree of risk implicit in most standards in any reliable way. This is due in part to the lack of clarity of objectives, in part to the widespread use of "safety factors" which introduce reductions in risk levels that are not quantifiable with any confidence and in part to deficiencies in our fundamental understanding of impacts of chemicals on humans and the environment. The report recommends that the option of developing explicitly risk-based EALs for sole use in BPEO assessments should be carefully considered. An example of such an approach is outlined in detail. Moreover, further consideration should be given to the proposal that human and environmental assessments should be undertaken separately in the BPEO framework and that the process option comparison is based primarily on the environmental evaluation. This would be justified by reference to a provision that all discharges should meet Standards which imply a "negligible" effect on humans.

In addition to the above, the feasibility of developing a standards database for HMIP was investigated.

# 1. INTRODUCTION

## 1.1 Background

Under Part 1 of the Environmental Protection Act (1990) covering integrated pollution control (IPC), Her Majesty's Inspectorate of Pollution (HMIP) is responsible for regulating releases to the environment from the most potentially polluting industrial processes in England and Wales, to ensure that the environment is protected. The IPC concept requires the evaluation of industrial releases to all media within the environment (air, water and land). The objectives of IPC are to prevent or render harmless the release of substances that may cause harm in any one of these media, such that effects on the environment as a whole are taken into account. This is achieved by the application of Best Available Techniques Not Entailing Excessive Cost (BATNEEC), having regard for the Best Practicable Environmental Option (BPEO). BPEO applies where substances are discharged to more than one medium and can be defined as:

> *"the option which in the context of releases from a prescribed process, provides the most benefit or least damage to the environment as a whole, at acceptable cost, in the long-term as well as the short term".*

HMIP uses environmental Standards in authorising releases and enforcing regulations to protect the environment from pollution. Also in order to identify the BPEO, HMIP uses environmental Standards as comparator values against which the concentrations in different environmental media resulting from releases, can be compared and their relative significance assessed. However, Standards derive from a variety of sources and differences in their basis, their derivation and the extent to which risk is assessed in each procedure makes their use in identification of the BPEO complicated and potentially unreliable. Therefore, a consistent basis is ideally required for the setting of environmental Standards if they are to be used in BPEO assessments. The main purpose of this study is to assess the current status of Standards in the UK and the extent to which a more consistent risk basis could be found.

## 1.2 Approach to project

This report aims to address the above issues by reviewing the "state-of-the-art" in Standard setting and identifying options for the development of a more consistent approach. In order to do this, the underlying procedures of various sources of environmental Standards (e.g. European Directives) have been reviewed to identify common elements to Standard setting in terms of derivation and extent to which risk to the environment is assessed. Standards for drinking water and worker safety have been included as, although not HMIPs responsibility, they are nonetheless relevant to human risk assessment and give an indication of how "risk" is implicit in other procedures.

The list that follows this introduction gives the sources of Standards which have been examined in detail as "case studies" (marked by asterisks) and those sources for which

methods have been reviewed to determine the underlying assessment of risk in different procedures (marked by crosses). Statutory environmental standards applicable to HMIP are displayed in Appendix D.

The main report assesses the way in which environmental Standards are currently used by HMIP and recommendations are made as to how the existing approach could be improved. The potential usefulness of a database of environmental standards to HMIP is assessed and conclusions and recommendations made.

## 1.3 List of all sources of Environmental Standards

### 1.3.1 Water

1. Dangerous Substances Directive (76/464/EEC) and associated UK Regulations (List I EQSs) *

   UK Legislation arising from Dangerous Substances Directive (i.e. List II EQSs outlined in DoE Circulars) *

2. National Rivers Authority operational EQSs*

3. Other National Organisations (e.g. US EPA, Canadian Council of Ministers for the Environment and Netherlands Ministry of Housing, Planning and the Environment) +

4. WHO Drinking Water Guidelines +

5. Freshwater Fish Directive

6. Shellfish Directive

7. European Union (EU) Directives relating to the protection of targets other than aquatic life (e.g. water intended for abstraction to potable supply, water intended for human consumption)

### 1.3.2 Land

1. EU Directive and UK Regulations relating to the use of sludge in Agriculture *

2. US EPA Part 503 Regulations for Sewage Sludge Applied to Land (risk based Standards) +

3. Netherlands Ministry of Housing, Planning and the Environment - Guide Values and Quality Standards for use in assessing soil contamination +

4. Danish Environmental Protection Agency - Soil Quality Criteria +

5. German National Standard DIN19730 - Soil Action Levels +

6. WHO - Guidelines for sewage sludge recycling currently under development +

7. UK DoE Interdepartmental Committee on the Redevelopment of Contaminated Land - Trigger Concentrations +

8. DoE developing risk-based contaminated land criteria

### 1.3.3 Air

1. Expert Panel on Air Quality Standards (EPAQS) *

2. Health and Safety Executive Occupational Exposure Limits*

3. EU Directives for specific substances *

4. World Health Organisation Air Quality Guidelines for Europe *

5. Other Standard setting International Organisations e.g. United Nations Economic Commission for Europe, convention on long range transboundary air pollution (UNECE Protocol) - critical loads/levels +

6. Blueprint for protection of the terrestrial environment +

7. Other national sources (e.g. US IRIS database) +

* Sources of Standards identified for detailed examination as case studies

\+ Other sources of Standards for which derivation procedure has been reviewed

# 2. STATE OF THE ART OF ENVIRONMENTAL STANDARDS IN THE UK

## 2.1 Introduction

Environmental Standards are set with a wide range of objectives for water, air and land. Such objectives are not always explicit but can include protection of human health, particular uses of the environment as well as more general descriptions such as structure and function of different ecosystems. The varied targets and objectives for protection within the different media has led to Standards that vary widely in their method of derivation, the level of implicit risk (in terms of increased risk of harm to individuals, population or ecosystems) and mode of expression of the Standard. However, on detailed study it is possible to identify aspects of Standard setting that are common to all procedures and these are discussed later.

### 2.1.1 Availability of Standards

Environmental Standards set by a variety of organisations for the protection of various targets against the adverse effects of chemicals in different media, have been listed in detail elsewhere (HMIP 1990, Flower and Alfonso West 1995). This section summarises the availability of Standards for different chemicals and media.

The medium for which most Standards are available is air since Occupational Exposure Limits (OELs) have been established for a large number of inorganic and organic substances by the Health and Safety Executive (HSE). These are intended to minimise risks to humans as a result of exposure in the work place. It is important to note that the values are not all derived from toxicological data some, for example, derive from irritant responses. In addition, air quality guidelines have been set by the World Health Organisation (WHO) for 27 substances with the intention of identifying acceptable risk levels for the human population exposed to atmospheric pollutants. In comparison statutory air Standards arising from EU directives have been set for only a few atmospheric pollutants (e.g. lead, sulphur dioxide, etc). The majority of air Standards are established to protect human health, with very few Standards set for the protection of ecosystems against direct effects of atmospheric deposition. Having said this, the United Nations Economic Commission for Europe (UNECE), Convention on Long Range Transboundary Air Pollution, have adopted an elaborate protocol for the protection of aquatic and terrestrial ecosystems against the adverse effects of atmospheric deposition of chemicals, whereby "Critical Loads" in the form of maximum deposition quantities are calculated on the basis of effects data for biota on land and in water. This approach goes some way to multi-media environmental protection.

In the UK, Standards for water exist for around 35 List I and II chemical substances (mainly metals and organics such as pesticides) as a result of the implementation of the EU Dangerous Substances Directive (CEC 1976). The Standards are mainly set for the protection of fresh and saltwater life, although other water uses such as abstraction to

potable supply are considered. Furthermore, a number of operational Standards for the protection of aquatic life have been proposed by WRc for the National Rivers Authority (NRA). A larger number of Standards have been set by the US EPA for the protection of aquatic life, although often the absence of the data underlying these Standards makes critical assessment of the values difficult.

The medium with the fewest established Standards is land. In the UK, the only statutory standards adopted are those set for the six metals identified in the EU Sludge Directive (CEC 1986) and the DoE Code of Practice (UK DoE 1989). These Standards aim to protect the soil ecosystem and man as a result of the agricultural use of sewage sludge. Soil Standards for organic substances are much scarcer due to paucity of the dataset and inherent difficulties in deriving Standards for organic substances whose behaviour in soils is less well studied and which are likely to biodegrade over long time periods. Standards for soils are available from other countries and contaminated land trigger values are available in the UK. These are discussed in more detail later. The recent Royal Commission report "Sustainable use of soil" recommends that soil be accorded equal priority with air and water as the second of five principles it advocates. It calls on Government Departments to give "proper weight to damage that can be caused to soil when pollutants are released to air and water" particularly in relation to the setting of Standards (RCEP 1996).

### 2.1.2 Quality and accuracy of existing Standards

The quality and accuracy of the different Standards available is difficult to establish. Ultimately a standard can only be as good as the data on which it is based. Data reliability and relevance to the objective is, therefore, the key to how adequately it fulfils its purpose.

Standards protecting human health can be quite explicit in their objective. For example, for chemicals which have threshold effect levels both WHO Drinking Water Guidelines (Appendix A3.4) and HSE Occupational Health Exposure Limits (Appendix C2.2) set numerical limits which should not cause appreciable health risk over a lifetime exposure. Also for genotoxic carcinogens where it is assumed that any exposure constitutes increased risk the acceptable level of risk has to be explicitly stated. For example, WHO Drinking Water Guidelines for genotoxic carcinogens are presented as the concentration in drinking water with an estimated excess lifetime cancer risk of $10^{-5}$, which equates to the risk of one additional cancer case per 100 000 of the population ingesting drinking water containing the substance, at the guideline value for 70 years. When objectives are stated this explicitly it is easier to assess the relevance and reliability of the data available to them. However, expert judgement is still important as, for example, chemicals which are carcinogenic to laboratory animals are not necessarily carcinogenic to man. The duration over which a standard is measured, and method of exposure are also crucial to the selection of the most appropriate data.

Protection of human health is straightforward compared to protection of the environment. This is because it relates to protection of the individual whereas the objective of environmental standards is far less certain. There is general acceptance that reduction in species richness is undesirable but the level which is tolerable is highly site specific and depends on the complex interactions between individuals, populations

and communities which determine the structure and function of ecosystems. The objective of environmental standards for water, for example, can probably best be defined as the protection of functioning and long-term health of the ecosystem. Generic standards must therefore either be set at a level which is protective for all likely scenarios (and hence over-protective in some situations), or must provide a compromise level of protection which is adequate for most scenarios. The UK and Canadian approaches accept that our understanding of the basis of this objective is still limited and to achieve a broad-based protection of complex ecosystems, aim to protect all aquatic life by protecting the most sensitive life stages of the most sensitive species. The US EPA and Dutch authorities, on the other hand, aim to meet the above objectives by protecting 95% of species, under the assumption that a 5% loss of the most sensitive species will have no adverse effects on ecosystem functioning and health. Standards can also take some account of likely exposure by relating the numerical limit to bioavailable forms (e.g. some metal standards for both soil and water are pH related, and water standards for metals are often expressed in the dissolved 'bioavailable' form) and particularly sensitive species (e.g. distinctions between salmonid and cyprinid fish for metal EQSs).

In order to reasonably identify sensitive species most standard setting approaches require a minimum data set covering a range of taxa. An understanding of the chemistry of a pollutant and its behaviour in the environment is also fundamental to determining the reliability and relevance of toxicity data to the standard setting process. Standard setting procedures will also use laboratory protocols and peer reviews as quality assurance procedures to judge data reliability and the standards themselves. The quality of the data used in the derivation of the different environmental Standards is, however, not always clear. This is particularly true for air Standards. In contrast, the data underpinning Standards derived for the protection of aquatic life by all the organisations identified in this review (e.g. DoE, US EPA, CCME, RIVM - Appendix A) undergo a degree of quality assessment before being used to set the Standard. For example, the toxicity data underlying the Standards derived by WRc for DoE and NRA are subject to a rigorous critical assessment and only data that meet certain acceptable quality criteria are used to derive Environmental Quality Standards. With regard to soil standards, there are no formal guidelines against which the quality of data can be assessed.

Also, where possible environmental standards are validated against field data. However, this is often of limited value because of the complexity of environmental interactions and because monitoring data are not sufficiently integrated to enable definitive conclusions to be drawn. Field data may indicate that a standard may be overprotective where a healthy community exists at concentrations above the Standard, but unless there is reliable information relating to the available margin of safety, there are often insufficient field data to enable the standard to be revised with confidence. For example, field trials have demonstrated the safety of UK statutory limits for potentially phytotoxic metals (Appendix B2) and although actual LOAELs have not been measured by realistic field experimentation, the absence of yield reductions in field trials on historic site soils with soil concentrations several times the current limits suggests that there is a high although undefined margin of safety. For water EQSs biological and chemical monitoring is often not sufficiently co-ordinated to attribute biological effects to concentrations of contaminants in the field.

## 2.2 Consistency in basis of environmental standards

Although environmental Standards are derived to protect a variety of targets, the procedures followed can all be considered to fit into a general standard setting framework. This framework can be summarised as follows:

1. **Objective:** Selection of general objective. i.e. use or attribute that is to be protected.

2. **Target:** Selection of specific target (for example an organism) and a response or end-point for the chemical concerned, which can be used to characterise the general objective.

3. **Data:** Collect data and information relevant to the target and end-point identified, apply quality judgements and appropriate manipulation and/or analysis.

4. **Derivation:** Apply a procedure to convert the data into a Standard. This usually involves the use of safety factors or statistical models.

5. **Validation:** Compare the derived Standard with real world experience and revise if necessary. This is the stage at which cost benefit considerations are sometimes brought to bear.

The procedures adopted to derive environmental standards vary in their approach both across and within media. In part this is due to the fundamental differences in the dynamics involved in the media. Air is transient with transit times of the order of minutes to hours. Soil is essentially static, with transit times measured in terms of centuries, while water is intermediate. But it is also due to the different objectives of the Standards (i.e. targets for protection). For example, as discussed in the previous section, in setting air Standards, humans are often the target for protection and risk is assessed at the level of the individual, while in the case of Standards for the protection of aquatic life, the target is usually considered at the population level. Despite these differences, an examination of Appendices A, B and C indicates that the procedures used to derive Standards for water, soil and air all have the following common elements within the broad framework indicated above:

i) All employ an extrapolation procedure to derive Standards on the basis of laboratory and/or field effects/no-effects data.

ii) Uncertainty in the extrapolation is accounted for to some extent in the procedure.

iii) The extrapolation for each Standard is based on one or more of the following:

   - application of a safety factor (or use of inherent margin of safety) to the lowest no effect level for the most sensitive species (e.g. aquatic and soil organisms or humans exposed through air)

- use of statistically derived species-sensitivity distributions based on dose-response data, to calculate a percentile protection level (e.g. 95% of all species. e.g. aquatic and soil organisms)

- Use of more refined computer models to assess risks to different sensitive receptors exposed via different pathways (e.g. humans and animals exposed via uptake of soil, plants, drinking water and air)

Methodologies utilising safety factors appear to be used most widely in setting Standards for water and air, particularly where data are too limited to adopt a more statistically robust approach. Indeed, the use of safety factors is the only method by which standards are derived in the UK for the protection of aquatic life. In soils, safety factors are not usually applied directly to available toxicity data, particularly when assessing the effects of sludge use on agricultural land. Instead, tests are conducted using pHs of 6-7, sensitive coarse textured soils and sensitive crop species which will result in a worst case estimation of metal accumulation in crops and the implicit safety margin for other scenarios is considered adequate (Appendix B2). The exception to this is the approach adopted in Denmark where safety factors are applied to the results of toxicity tests that involve application of metal salts direct to test soils. However, this has led to Standards that are considerably more stringent than those set by other authorities.

The use of statistically calculated species-sensitivity distributions is most often associated with the calculation of 95% protection levels for the species in a given medium. The approach often uses the assumption of a log-logistic or log-normal distribution of laboratory data and of species sensitivity. It further assumes or postulates that loss of 5% of the more sensitive species in an ecosystem will have no long-term effects on ecosystem functioning and health. The method is used most heavily by the Dutch and the US. The Dutch have proposed its use for deriving Standards for the protection of water, soil and air (Sloof 1992). However in practice, toxicity data are often too limited to adopt this method and so both the Dutch and the US have a safety factor approach to fall back on.

More refined risk assessment models have been developed by the Dutch and the US to assess risks to humans and animals following exposure via various pathways to chemicals originating in soils (e.g. soil to plants to animals to humans). These aim to identify the most sensitive receptor and set a guideline which is protective of this. In addition, models are used by WHO to assess the risks posed to humans following exposure to genotoxic carcinogens in air and water.

## 2.3 The place of risk assessment in Standard setting procedures

A distinction needs to be made between a full risk assessment of a chemical in the environment and a risk basis to Standard setting. A 'quantitative' assessment of risk of pollutants in specific environmental media only occurs when measured or predicted exposure concentrations are compared with effects concentrations. In order to do this some real or postulated exposure scenario has to be used. In effect the risk assessment has to be a site specific activity even if "the site" concerned is rather large. The Standard setting procedure itself is largely concerned with the 'effects' part of a

chemical risk assessment exercise, although as explained in Section 2.1.2 there may be some qualitative consideration of exposure in terms of bioavailability, which is not site specific. This means that the Standard derivation has to be adequately protective in any location that may be of concern.

Chemical risk assessments are often only semi-quantitative where the exposure concentration is compared against a Standard that has no statistical basis, and the quotient (i.e. the ratio) is determined to assess the relative risks. This approach does not make any assessment of the probability and frequency of exposure concentrations and associated effects arising. However, the US EPA have developed an aquatic ecological risk assessment framework that incorporates probability and frequency parameters (US EPA 1992). This approach is discussed more fully in Section 2.3.3.

### 2.3.1 Standards for humans

Two approaches are usually adopted depending on whether chemicals have a threshold response level (hence, allowing 'no appreciable risk' to be defined) or whether occurrence at any level may represent risk to human health (genotoxic carcinogens).

Standards for humans exposed to genotoxic carcinogens are frequently derived using an explicit risk basis (e.g. WHO air and water guidelines, Occupational Health Exposure Limits) as detailed in Appendices A and B). The approach involves the application of various low dose extrapolation models usually with the aim of achieving a risk level of less than $10^{-5}$ excess cancer risk.

For non-carcinogenic substances the approach followed usually employs the application of suitable "safety factors" to toxicological data to define a level below which there should be no appreciable excess risk.

### 2.3.2 Standards for protection of the environment

As indicated previously there is no specific consideration of risk to the function and long-term health of ecosystems in the procedures currently used. While some countries set themselves a statistical target for protection, usually 95% of species, this cannot easily be linked to any particular level of ecosystem protection. This will depend on the importance of the 5% of species that are not protected and the degree of "redundancy" that the particular ecosystem concerned possesses. The risk assessment framework developed by US EPA for chemicals in the aquatic environment contains elements that can be exploited for application to Standard derivation. This framework is outlined in Section 2.3.3 below and in more detail in Appendix A.

### 2.3.3 US EPA approach to aquatic ecological risk assessment

This approach makes use of the same species sensitivity distributions adopted in the US and Dutch Standard derivation procedures where distributions of measured acute and chronic data are assumed to represent the universe of species and to be log-normal or log-logistic with respect to concentration.

In the US EPA framework, risk is quantified by the use of probabilistic expressions of effect end-points and exposure concentrations. This involves a comparison of probability distributions of measured environmental concentrations with probability distributions of species response data as determined in laboratory single-species toxicity tests or field studies. That is to say two curves are plotted; one of frequency of occurrence of environmental concentrations, and another of frequency of species sensitivity (e.g. acute or chronic effect/no-effects) against chemical concentrations. The overlap of these distributions is a measure of the risk to aquatic life. The degree of overlap of the exposure curve with the effects curve can be used to estimate the probability that a percentage of species will be adversely affected on a percentage of occasions.

This approach has a number of advantages over non-probabilistic assessments using single hazard quotients based on the response concentration for the most sensitive species and the maximum environmental concentration. Most importantly, it uses all available data and makes an estimation of the magnitude and likelihood of potential ecosystem impacts as opposed to just "worst case scenarios". However, the approach is "data-intensive" and is most credible where a large dataset exists for both environmental exposure and toxic effect concentrations. Use of sensitivity distributions should ideally include a good spread of sensitive and less sensitive organisms in order to avoid a skewed distribution. Similarly, exposure concentration distributions require the inclusion of a range of locations and seasons on which varying concentrations may be dependent, again to avoid a skewed distribution curve. Soloman *et al.* (1996) outline the practical use of this approach to assess the ecological risks of the herbicide atrazine. This is an ideal test substance as it has a large dataset on toxicity and reported environmental concentrations, a clearly defined use pattern and a well developed understanding of its behaviour and effects under field conditions.

## 2.4 Level of risk assessment implicit in different derivation procedures

As outlined above, Standard setting is only concerned with the "effects" assessment component of a full quantification of risk of chemicals in the environment. In other words, Standard derivation only makes use of the species-sensitivity distribution as outlined by Soloman (1996) and not the distribution of exposure concentrations.

In the current approaches used to derive Standards, the extent to which assessment of risk is an inherent part of the procedures is not clear. Safety factors and statistical models are used to extrapolate from effect/no-effect concentrations obtained for a limited number of species in the laboratory, to no-effect concentrations for complex communities in the field or human populations. The current use of safety factors appears to be largely arbitrary, although work is on-going to refine the figures and make them more scientifically robust (e.g. ECETOC 1993). Moreover, while the use of statistical models would appear to have more of a defined risk basis, the assumptions made about the results of such models (e.g. that 95% protection of species in a community will protect ecosystem functioning and long-term health) are generally unproven and appear to have little scientific basis. In other words, the percentile protection level chosen is apparently arbitrary. To make such statistical

expressions of Standards truly risk based, would require some statement about the level of ecosystem function or other objective that is protected in this way.

Therefore, while the expression of Standards derived following these procedures sometimes allows for a qualitative recognition of risk acceptability associated with different exposure scenarios, uptake routes, bioavailability, etc (examples are given in detail in appendices A to C), the 'true' risk to organisms is not actually quantified in the procedures themselves. This would be useful in order to assign similar expressions of risk to standards associated with different environmental media. Such an exercise would provide a common currency for comparing relative risks posed by toxic substances to all media.

It may be possible in general terms to associate a 'quantitative' expression of risk with each safety factor applied in Standard setting procedures. For example, an acute LC50 for fish is in itself an expression of risk, in that at a specific concentration 50% of individuals in a test population are expected to die in a given exposure period. Therefore, if the shape of the dose-response curve is known, it may be possible to extrapolate back to the acceptable risk level (e.g. one fish mortality per n individuals) associated with the derived Standard, following application of a particular safety factor to the acute LC50.

Since such an assessment of the risks associated with the different safety factors is clearly dependent on the dose-response curve, the use of effects data such as L(E)C5, L(E)C10 and L(E)C50 values which are interpolated from the dose-response plot, is likely to be more meaningful than the use of a No-Observed Effect Concentration (NOEC) which is simply the highest concentration tested at which effects are not statistically different to those observed in the control. Chapman *et al* (1996) have reported that the NOEC is not a good measure of the real concentration causing no effects and that use of L(E)C50s or other point estimates are more consistent, more reliable and less variable than NOECs. They make the point very forcefully that NOEC values are not appropriate for regulatory use, a point which we support. Unfortunately, the use of NOEC values is widespread and may be a custom that is difficult to change.

# 3. USE OF ENVIRONMENTAL STANDARDS BY HMIP

## 3.1 Current use of Environmental Standards by HMIP

Under Part 1 of the Environmental Protection Act 1990 Integrated Pollution Control (IPC) was introduced as a framework for controlling releases from certain prescribed industrial processes and ensuring compliance with relevant EC Directives on pollution control. HMIP is responsible for regulating prescribed processes in accordance with IPC and operators of these processes are required to obtain a written authorisation to operate from HMIP.

HMIP uses environmental standards in three main ways in order to assist it in delivering its regulatory commitments:

1. Compliance with numerical limits necessary to enable the UK to fulfil international agreements (e.g. EC Dangerous Substances Directive 76/464/EEC);

2. Strategic decision making about pollution control policy;

3. As Environmental Assessment Levels for the following purposes:

    - in Environmental Assessments for IPC processes to determine harmlessness;
    - in BPEO assessments to determine the option which minimises pollution to the environment as a whole;
    - to prioritise waste streams for waste minimisation projects.

### 3.1.1 Compliance with numerical limits and strategic decision making

In regulating emissions from prescribed processes HMIP must place conditions within an authorisation to ensure that releases do not cause, or contribute to the breach of:

- any direction given by the Secretary of State to implement European Community or international obligations relating to environmental protection;
- any statutory Environmental Quality Standard or objectives or other statutory limits or requirements.

Statutory levels and standards used for policy formulation are generally outside the control of HMIP. Statutory standards are listed in Section 2.1.1.

### 3.1.2 Use of standards in environmental assessments

The Environmental Protection Act 1990 requires Best Available Techniques Not Entailing Excessive Costs (BATNEEC) to be used to prevent and minimise releases of prescribed substances and to render harmless any substances which are released and which might cause harm. Within the context of the Act 'harm' is defined as:

> *"Harm to the health of living organisms or other interference with the ecological systems of which they form a part and, in the case of man, includes any offence to any of his senses or harm to his property".*

However, the Act does not define the nature of effects which may be considered harmful or the level in the environment at which they may occur. An environmental assessment is thus necessary to evaluate the impact of releases. In its simplest form an environmental assessment comprises of three stages:

- characterisation of emissions;
- exposure assessment;
- effects assessment.

If this process were to be undertaken in full for every release it would pose a significant burden on industry, HMIP has thus developed a more pragmatic approach. They assume that single medium environmental standards or guidelines act as a surrogate for a full analysis of the transport of a pollutant through the environment and its subsequent impact on a specific receptor. Where releases to different media occur the results of substance/medium specific assessments can be brought together to determine the Best Practicable Environmental Option (BPEO) by the procedure described in Section 3.3. Under these circumstances environmental standards are required to enable comparison between the relative impact of releases to different media.

HMIP has developed medium specific Environmental Assessment Levels (EALs) for substances which can be used as comparators to assess the relative significance of emissions to different media. EALs are used in environmental assessments in the following way:

- Where statutory Environmental Quality Standards (EQSs) exist the EAL is set at an equivalent level. Exceedance of the EQS is considered 'intolerable', lower concentrations are considered tolerable and process contributions less than 0.2% of the EAL are considered insignificant. Within the tolerable region, BATNEEC should be used to prevent, minimise and render harmless prescribed substances and to render harmless other substances. Releases are defined as priorities for control if the process contribution exceeds 2% of the EAL or if the predicted environmental concentration resulting from the release exceeds 80% of the EAL.

- Where statutory EQSs are not available for the substance being released the emission is considered tolerable, and BATNEEC is used to prevent, minimise and render harmless prescribed substances and render harmless

other substances. EALs are derived from published information, such as international standards or guidelines or from toxicological information using expert judgement. The same judgements are applied on significance and tolerability as those used when EQSs are available, except that there is no 'intolerable' level.

HMIP have identified a number of characteristics which environmental standards should possess if they are to fulfil their role in environmental assessments and BPEO:

i) be based on the sensitivity of particular habitats or receptors (e.g. human health, protection of natural ecosystems and protection of specific sensitive receptors);

ii) be produced according to a standardised protocol;

iii) provide a similar, defined level of protection for different receptors both within and between media.;

iv) take account of habitat specific environmental factors;

v) provide information on the dose/response curve to enable judgements to be made on any deviation from the standards;

vi) take account of temporal aspects of impacts (e.g. acute or chronic exposure).

However, a suite of consistent standards with these properties is not currently available. As an example, out of approximately 460 chemical substances encountered by HMIP, there are only around 40 established standards for releases to air commonly in use in the UK (27 substances assigned 1987 WHO guideline values, 6 EPAQS values, 4 UNECE Critical Levels for Vegetation and 4 Statutory EQSs). Of these standards, a number are related to a single substance (e.g. standards for $SO_2$ have been established by EC, WHO, EPA QS and UNECE) and often provide different levels of protection for different receptors. In deriving EALs HMIP adopts a simple and transparent procedure but recognises that they do not necessarily provide comparable protection between different media as, for example, EALs for air are derived from occupational exposure standards which protect human health, whereas those for water and land are largely based on standards set for the protection of the natural environment. Although the emphasis is on long term effects, and hence long term EALs, short term EALs are also derived. The derivation procedure is examined in more detail in Section 3.2.

### 3.1.3 Use of standards in BPEO assessments

BPEO is applied to releases from prescribed processes where substances are released to more than one medium. BPEO is defined by HMIP as:

*"the option which in the context of releases from a prescribed process, provides the most benefit or least damage to the environmental as a whole, at acceptable cost, in the long term as well as the short term".*

HMIP adopts the following approach to evaluate the BPEO:

The direct environmental effect of a substance released to a particular medium is assessed as the ratio of the process contribution (PC) to the EAL for that substance in a particular medium and is termed the Environmental Quotient (EQ) for that substance in that medium.

$EQ_{(substance,medium)} = PC/EAL$

Environmental Quotients are calculated for each substance released for the relevant medium.

The Environmental Quotients for each medium (air, land, water) are summed to give an overall Environmental Quotient for each medium, these in turn are summed to give the Integrated Environmental Index (IEI) for that option.

The Best Practicable Environmental Option (BPEO) is selected by comparing EQS and IEIs as appropriate, although an initial ranking based on these may be modified to take into account other considerations, such as the hazard of waste, which are not released to air or water and production of greenhouse gases and ozone.

The operator may choose to implement the BPEO. However, if the operator wishes to justify the choice of some other option an economic assessment is undertaken.

### 3.1.4 Use of standards for waste minimisation

There is no set approach to using standards to prioritise waste streams for waste minimisation. However, this is similar in principal to the use of EALs to determine the BPEO but focuses on the contribution arising from individual waste streams rather than the plant as a whole.

## 3.2 Derivation of EALs

### 3.2.1 EALs for releases to air

Where EQSs for air are not available the following sources, in order of preference, are used:

1. Expert Panel on Air Quality standards (EPAQS)
2. EC Guideline values
3. World Health Organisation Air Quality Guidelines for Europe (1987)
4. Other International Organisations (e.g. UNECE)
5. Other National Organisations (e.g. US IRIS database)
6. Health and Safety Occupational Exposure Limits
7. Expert judgement

For consistency, risk based values proposed by the World Health Organisation or on the IRIS database are excluded. The number of established environmental standards available are limited and most EALs have been based on occupational exposure limits. Time-weighted 8-hour occupational exposure limits assume 40 hours/week exposure (8 hr x 5 days) and an average working year of 44 weeks to give an annual exposure of 1760 hours over their employment lifetime. The general population could however theoretically be exposed over their whole life so HMIP use the following safety factors to allow for this in the calculations of long term EALs:

- Maximum weekly exposure is 168 hours (24 hours x 7 days) over 52 weeks/year to give an annual exposure of 8736 hours/year. This is a factor of 4.96 over the occupational exposure limit. HMIP allow an additional safety factor of 2 to allow for the fact that there may be no recovery period between exposure sessions giving an overall factor of 10 on the occupational exposure limit.

- An additional safety factor of 10 is allowed for more sensitive individuals (based on WHO 1994 who state that a factor of 10 is normally used to allow for differences between the population mean and the response of sensitive individuals)

- EALs are therefore usually set at 1/100 of the 8-hour OES

- However, for some substances maximum exposure limits (MELs) are specific for occupational exposure either because they are of particular concern (e.g. a carcinogen) or because there is some doubt about the actual No-Observed Adverse Effect Level (NOAEL). HMIP assumes that compliance with MELs effectively requires the average concentration to be controlled to approximately 20% of the maximum. Therefore, an additional safety factor of 5 is applied to those chemicals listed as having a MEL in HSE Guidance Note EH40/94, resulting in an overall safety factor of 500 on the 8-hour OES.

Where no short term environmental standards exist from sources 1-5, short term EALs are derived according to the same approach as above but using 15 minute Short Term Exposure Limits (STELs) set by HSE, and where STELs are not listed, then a value of 3 times the 8-hour time weighted average may be used (HSE 1994). The following approach is adopted to derive short term 1-hour EALs:

- no additional safety factor for increased exposure is necessary;

- a factor of 10 is sufficient to allow for sensitive individuals, and sufficient to allow for differences in concentrations averaged over 1 hour rather than 10 minutes;

- where the substance has a MEL an additional safety factor of 5 is applied.

### 3.2.2 EALs for releases to water

The following sources of information are used to identify EALs, where there is more than one source for a substance then the source nearest the top of the list is used:

1. EU Directives (other than those implemented through UK Regulations);
2. National Environmental Quality Standards;
3. Proposed National Environmental Quality Standards;
4. NRA Operational Guidelines (EQSs);
5. Relevant National or international organisations (e.g. US EPA, WHO);
6. Expert Judgement.

In general EALs are based on sources 1-4.

### 3.2.3 EALs for releases to land (via deposition)

The establishment of critical loads for sulphur and nitrogen has taken considerable scientific investigation. A more pragmatic approach has thus been used to set EALs for soil which involves identifying existing soil quality standards and back calculating a maximum deposition rate (MDR).

The sources of information used, in order of preference, are:

1. UK DoE sewage sludge disposal code of practice;
2. UK Contaminated land trigger values;
3. MAFF recommendations;
4. International guidelines
5. Other overseas national guidelines;
6. Expert Judgement

It is recognised that this approach is far from satisfactory as many of the standards available from these sources have been developed for a particular purpose and may not be directly applicable to the assessment of deposition from industrial processes. The following assumptions are made in calculating a MDR:

- The MDR is defined as the quantity of pollutant which can be added to the soil daily over 50 years before the selected soil quality standard is exceeded.

- For organic pollutants it is assumed that the ambient soil concentration is zero and that soil concentrations declined according to a first order decay rate.

- For inorganic compounds the soil quality standards are corrected for the median ambient soil concentration and no allowance is made for degradation or other removal processes.

The provisional MDR is calculated from

$$MDR = (SQC-AMB_s) * D_s*d_s / T$$

and the MDR taking into account the 1/2 life of substances was calculated from:

$$MDR = SQC * a * D_s *d_s / (1-e^{-aT})$$

where;

MDR = provisional maximum deposition rate ($mg/m^2/day$)

SQC = selected soil quality standards (mg/kg dry soil)

$AMB_s$ = median soil pollutant concentration (ambient soil concentrations derived from Davis 1980 and McGraph and Loveland 1992)

$D_s$ = soil density ($1000\ kg/m^3$)

$d_s$ = mixing depth for pollutant (7.5 cm)

T = evaluation period over which deposition occurs

a = disappearance rate of the chemical in the soil related to half life ($t_{0.5}$) by ($\ln 2/t_{0.5}$)

# 4. THE NEED FOR, AND FEASIBILITY OF, A STANDARDS DATABASE

There is an obvious need for HMIP inspectors to have access to the most up-to-date standards available when undertaking IPC assessments. There may also be a benefit in providing access to this for industry and the general public to aid transparency.

As explained in Section 3, HMIP's requirements can be divided into three main areas:

1. compliance with statutory limits;

2. strategic decision making;

3. as Environmental Assessment Levels for the following:

    - to assist in undertaking single media environmental assessments
    - to act as comparators in determining the BPEO
    - to enable prioritisation of waste streams for waste minimisation

## 4.1 The Substance Information System (SIS)

The aim of this system is to present an Agency view on a wide range of substance related issues. The data hierarchy is organised so that an 'opinion' of an organisation on a substance (e.g. a standard or guidance) is entered onto the database. An expert panel will be used to place an interpretation on standards promulgated by different organisations and the available data on substances to provide an Agency view on a substance and guidance for Agency personnel.

Standards will be only one aspect of the data held on a substance in SIS. Other aspects include:

- priority lists, inventories and registers of relevance to the Agency;

- substance classifications;

- relationships between substances (e.g. Dioxin congeners);

- substance specific information (e.g. sources, manufacture, uses, ambient concentrations, physico-chemistry, environmental fate and behaviour, toxicology, bioaccumulation).

SIS is currently in the first of two stages of development. This stage is developing a database for data maintenance. Data entry screens are organised on an 'organisation' basis. For example, one organisation might be the US EPA. To enter information on a standard for the US EPA you would first identify the appropriate scheme e.g. - Ambient Water Quality Standards and then extract the relevant information on the standard in the different fields presented.

Stage 2 of development, the development of enquiry screens for use by HMIP Inspectors and the means of delivery (e.g. CD ROM or IPCIS), has yet to be specified. These will, however, need to deliver information to inspectors on a substance by substance basis.

Where statutory standards for individual substances are not available, inspectors will need guidance on which standards to use in preference to others when undertaking environmental assessments. If EALs are set for most substances, the process could be simplified by defining the EAL scheme and entering all EALs set by HMIP, perhaps along with other substance information. Inspectors would only then need to search for standards set by other organisations where EALs were not set for a substance or where further information was needed.

## 4.2 Other standards databases

W S Atkins prepared a register of Risk Assessment Tools for use by the Environment Agency (Flower and Alfonso West 1995). This listed air, water and land standards/guidelines available at the time of publication. This is a useful compilation of standards available of substances of concern to the Agency. The necessary brevity of information provided may, however, occasionally preclude an adequate understanding of the basis of these standards and their applicability, and whether they are current or not. An example which illustrates the potential importance of this are the SNARLs quoted in the report. WRc derives Suggested No Adverse Response Levels for use by the Water Industry when responding to pollution incidents which may impact on potable supplies, and has a database of these which is continually updated so that each SNARL is re-evaluated every three years. The information on SNARLs in the Atkins report has identified values which WRc supplied exclusively for use in the PRAIRIE model specifically for the River Dee catchment in phases over 1991,1993 and 1994. Where information indicated a substance could be detected by consumers at concentrations lower than those derived from toxicological data this organoleptic data was used to set the standards, rat LD50 data were included as a parameter for the PRAIRIE database but were not necessarily the basis of the SNARL. SNARLs derived for use in a planning tool would not necessarily be appropriate when trying to assess the risk of contaminants in potable water to human health in an emergency. Of the approximately 250 chemicals for which SNARLs were provided, 140 were provided in 1991 or 1993 and would therefore now be considered out of date and of the remainder about 1/3 have subsequently been updated. In order to overcome these concerns it has been agreed with the PRAIRIE Software Development Group that the National Centre for Environmental Toxicology, at WRc, will hold a master database of SNARLs which will be used to periodically update PRAIRIE.

The National Centre for Environmental Toxicology at WRc has developed a database of Environmental Quality Standards (EQSs) for water which is currently used by NRA staff, Scottish RPBs and DoE Northern Ireland as well as being available commercially. The object of this exercise was to provide an authoritative tool for use by pollution control staff which for transparency was also made commercially available. It provides information on numerical limits, their source, how they are expressed and how they should be monitored. As well as statutory standards, it lists

EQSs under development in the DoE and NRA programmes along with their status, and expansion is planned to include other environmental standards. The database also provides information on the Programmes from which the standards have arisen, along with associated priority substance lists (e.g. EC Dangerous Substances Directive, Freshwater Fisheries Directive, North Sea Conferences and PARCOM).

Currently no electronic transfer programme exists to transfer data into SIS, this may also be complicated because of the complexity of linkages between data fields in SIS.

## 4.3 Conclusions

- It would appear sensible to use the SIS as the ultimate delivery platform for standards and other information for Inspectors. However, other sources may be required prior to SIS becoming widely available.

- The organisation based approach to data entry in SIS is beneficial to enable easy identification of new standards promulgated by organisations and revisions of numerical standards to be auditable and transparent to inspectors.

- Enquiry screens for SIS have not yet been specified but these will need to deliver appropriate information on substances to inspectors.

- The key information on standards for inspectors will be Statutory standards and EALs, and the basis and applicability of these.

- Standards and other guidelines promulgated by other organisations is useful supplementary information for inspectors when the key information above is not available.

- Potential changes to the basis of EALs such as change to receptor specific rather than media specific should be flagged at an early stage as this could impact on the strategy for data organisation within the database.

- It will be important that standards are regularly updated on a periodic basis and a strategy to enable this to be done cost-effectively will need to be developed.

- It is likely that information on standards used by the Agency will need to be made publicly available for transparency. The Agency may, however, not wish to make the whole SIS database available and a parallel database of standards may therefore have some merit.

## 4.4 Recommendations

- At this stage it would appear sensible to populate SIS with information on standards rather than construct a separate database.

- SIS is organised to accept data entry by organisation, rather than by substance. Inspectors will however require information on a 'substance by substance' basis and appropriate connections will be required between data entry and enquiry screens.

- Data entry by organisation does however enable easier identification of new or amended standards and thus facilitates updating of the database.

- We would recommend that this should be done by a standard pro-forma. The detailed specification of this would need to be agreed with the SIM project manager. This would provide an auditable trail for data entry and allow verification that the data in the database is correctly entered for Quality Assurance procedures.

- We would recommend that the following information is among that included in the system:

  i) Organisation

  ii) Type of Standard

  iii) Status (e.g. Statutory standards should be clearly flagged)

  iv) Substance Name

  v) Date set

  vi) Numerical limit

  vii) Unit

  viii) QA rating

  ix) Period over which standard is applicable (1 hour, 1 year)

  x) Expression of standard (maximum, mean etc)

  xi) Measurement of standard (total, dissolved)

  xii) Analytical method associated with standard

  xiii) Basis of standard (toxicological data and safety margin implied)

  xiv) Author

# 5. ASSESSMENT OF OPTIONS FOR DEVELOPMENT OF CONSISTENT MULTI-MEDIA RISK-BASED STANDARDS

## 5.1 Introduction

The fundamental technical basis for the traditional view of environmental Standards has to be questioned. The hypothesis implicit in this traditional view, that for any substance an environmental concentration can be specified such that if this concentration is not exceeded there will be no environmental damage under any circumstances, is exceedingly difficult to support given our current poor state of understanding about ecosystem responses to chemicals, over long enough timescales to make ecosystem judgements possible. Similarly the associated concept that a rigid boundary exists between no (or an acceptable level of) risk and an effect at the level of the Standard is not supported by our current knowledge of responses to chemicals. In fact, current understanding says precisely the reverse, i.e. that no specific boundary exists and that risk and harm increases steadily as concentrations increase and that the precise responses depend on local conditions and circumstances. Nevertheless, Standards exist and more are needed to aid consistent decision making in relation to environmental protection.

The requirements of Integrated Pollution Control (IPC) specify that the environment as a whole should be protected and that harm to humans and their senses, their property, the environment and all organisms supported within the environment should be minimised. This is achieved by prevention, minimisation and rendering harmless of releases to air, water and land. In order to objectively compare releases to different media and ensure that the Best Practicable Environmental Option (BPEO) is identified, a consistent basis is required for the derivation of multi-media environmental Standards. This section considers options that could be followed bearing in mind HMIPs duties and functions.

In the past little attention in Standard setting and application has been given to the fundamental differences between elements such as heavy metals and organic chemicals. Yet elements are not destroyed by environmental processes merely recycled. Organic chemicals on the other hand are destroyed as part of the biogeochemical processing of carbon. These differences should be given more prominence in Standard setting and could be exploited in Standards for example by considering natural fluxes of the elements. These lines of thought deserve further consideration but are outside the remit of this study.

## 5.2 Use of Standards and EALs by HMIP

The current practice of HMIP is to use Environmental Assessment Levels (EALs) as comparator values against which the concentrations in different environmental media resulting from releases can be compared and their relative significance assessed. When

Standards are available these are used as EALs but where Standards are not available EALs are established by HMIP. It is useful at this stage to draw a distinction between statutory Standards that are imposed on HMIP and EALs which HMIP set in the absence of relevant statutory values, on the basis of other Standards derived by other parties. Statutory Standards imposed by regulatory authorities have to be met in any authorisations HMIP may establish. However, because these values are set with a variety of objectives in mind and adopt a variety of technical approaches in their derivation, they do not form a consistent basis for calculation of Hazard Indices and subsequent BPEO assessment. A solution to this problem may be to establish EALs with the explicit objective of equating risks across environmental media and use only these values in BPEO assessments. Standards imposed on HMIP would then as at present have to be met by all process options considered acceptable for inclusion in the BPEO comparison.

There is a further distinction that is worth considering between Standards and EALs. Standards are established without particular consideration of the source of the chemical. In fact it could be argued that Standards are primarily designed to protect the environment against multiple and diffuse sources. On the other hand EALs are concerned with point source control in mind. Thus whereas Standards have to be protective of all environmental conditions likely to be encountered including all species and ecosystems, EALs could have more site specific features associated with them. While this distinction may be worth considering at some stage, the concept of site specific EALs has not been considered further in this report.

## 5.3 Available options for the development of consistent multi-media risk based Standards

This section considers options for a more consistent approach to Standard setting in relation to HMIPs use of Standards as outlined above. The three basic uses that HMIP has for Standards are :

1. as statutory levels imposed by other organisations;

2. as a basis for various strategic decisions about pollution control;

3. as levels that are used for the basis of EALs.

In the first two cases the Standards HMIP use are generally established by other regulatory authorities. The scope for influencing the development of these values is therefore limited. The rest of this section will consider options for developing a more consistent basis for establishing EALs. However, the procedures described could apply equally to setting environmental Standards for other purposes and if adopted by HMIP would provide added force to move other authorities in the same direction.

The specific options considered are as follows:

1. Use of existing Standards and adjustment of values where necessary to bring about greater consistency

2. Use of an equilibrium partitioning approach on the basis of a single existing Standard

3. Use of an approach to EAL setting which is more risk based

### 5.3.1 Use of existing Standards

The information and analysis given in Section 2.0 indicates that existing Standards are derived using a variety of approaches, none of which are explicitly risk based. Despite the variety of approaches adopted, all procedures follow the same basic framework as outlined in Section 2.2. Within this framework, wide use is made of "safety factors" and "expert judgement" which makes it very difficult and uncertain to retrospectively estimate the risks implicit in the derivation procedure and thereby those risks associated with a Standard or group of Standards. It follows that attempting to develop and apply a procedure to make existing Standards more consistent will be difficult and uncertain. It may also be politically sensitive for HMIP to be seen to be "tinkering" with statutory Standards established and used by other bodies.

### 5.3.2 Use of equilibrium partitioning

As detailed in Section 2.0 and the appendices, Standards set for the protection of a specific medium are generally based on dose-response data for organisms representative of that medium. However, where relevant toxicity data are too limited to set a Standard for a particular medium, it may be possible to set the Standard by applying equilibrium partitioning to a value set for a different medium for which toxicity data are not so scarce. The Dutch have proposed an approach for doing this, whereby Maximum Tolerable Concentrations (MTCs) for the protection of soil and air organisms are derived by applying equilibrium partitioning equations to the MTC derived for aquatic life (Sloof 1992). However, this approach assumes that concentrations in the various media attain equilibrium - an unrealistically simplistic scenario very unlikely to exist for the vast majority of substances in the environment. Moreover, the organisms inhabiting one medium (e.g. water) maybe more sensitive than those inhabiting another (e.g. air). Equilibrium partitioning could therefore lead to the derivation of over protective Standards for other media. This approach does not appear to have been adopted in the Netherlands (Ministry of Housing, Spatial Planning and the Environment 1994), since its proposal in 1992 (Sloof 1992).

However, there may be a place for the equilibrium partitioning type of modelling approach as a means of checking the integration of multi-media Standards derived separately on the basis of dose-response relationships for organisms representative of each medium. In setting separate Standards to protect each medium, no consideration is given to inter-media transfer of pollutants. For example, compliance with an environmental Standard for air may not necessarily imply compliance with a Standard for the same chemical in water. This is because the air Standard is not concerned with the implications of atmospheric deposition to water. To over come this problem, Van de Meent and De Bruijn (1995) have suggested the use of SimpleBox, a Mackay type steady-state model for the harmonisation of multi-media Standards. This model predicts concentrations of pollutants in different media, taking into account parameters

such as emission, degradation, leaching, volatilisation, etc, and tests the 'coherence' of existing environmental Standards. In other words, the model determines the potential for exceeding a Standard in a 'secondary' medium even when ensuring compliance with the Standard for the 'primary' medium of concern. The authors admit that this approach needs considerable validation but justify its use as means of developing a more integrated approach to environmental protection by the lack of any suitable alternatives.

It should be noted here that the United Nations Economic Commission for Europe, Convention on Long Range Transboundary Air Pollution (UNECE), also attempts to integrate pollution control, by setting air Standards in the form of maximum deposition quantities of chemicals, on the basis of effects on aquatic and terrestrial ecosystems (see Section 2.1.1 and C3.1). However the chemicals concerned in these studies are very limited and the resources required to establish critical loads would be prohibitive for the number of chemicals on the Chemical Release Inventory (CRI).

### 5.3.3 Use of an analytical risk based approach for the derivation of EALs

This option involves a new approach based on the Standard setting framework presented in Section 2.2. It explicitly introduces a risk basis and incorporates and carries risk and uncertainty analysis through the different stages involved. The approach is fairly straightforward in concept giving it transparency and is defensible from a technical and an historical perspective. With appropriate development as outlined below, it will also enable progress to be made when data are scarce. Use of the system depends critically on the specification of the objective which, for the purposes of setting EALs, will need detailed consideration by HMIP. The description of subsequent phases in the outline below has to be given in rather general terms to allow for the detailed objective that HMIP will establish. The major stages in this proposed approach are as follows.

#### Statement of objective

For Standards in general this statement should identify the use or the attribute of the environmental medium that is to be protected and the level of protection that is to be aimed for i.e. the level of risk acceptability involved. As indicated earlier, it is this stage which is often missing or not explicit in existing Standards. An example for an area of land may be that there should be no more than a 1% deterioration in crop productivity in the next 100 years and we should be 95% confident of this. The objectives are likely to be derived at least in part by political judgement, as many of the objectives have been in the past for the Standards reviewed in the appendices. For the derivation of EALs an objective would be needed that states that the risks posed to the different media are equal and tolerable.

It would probably be desirable from HMIPs perspective to have objectives that protect all potential targets in the environment, so that a single Standard exists for cadmium, for example. However, this does not seem possible at present mainly because the protection of humans is targeted at the individual level, while that for the environment is targeted at the ecosystem population or function level. The best approach seems to

be to recognise this basic distinction and to have two sets of Standards one with the objective to protect humans and the other to protect the environment. This approach is consistent with EC Council Regulation 793/93/EEC on the evaluation and control of risks posed by existing substances and the risk-benefit framework advocated in guidance published by DoE (DoE 1995) which deals separately with human and environmental risks and assigns economic values to these risks. In the longer term it may be possible to use such economic evaluations, to equate risks to humans with risks to environmental attributes. For example, a one in a million risk to human life can be given a value which could be compared to the value and risk implied for a population of fish or for crop production. In the much longer term it may even be possible to extend the concepts of ecosystem function to include man, but this is far beyond the immediate horizon.

Standards for man could be set for a specific risk level applied at the individual level in much the same way as is done currently with an acceptable risk level identified. Often a figure of one in 100 000 or one in a million per year is used.

One alternative to establishing a set of EALs for the protection of humans is to require that the BPEO option should not for humans entail a level of risk higher than that implied by an environmental Standard. This may mean that HMIP would need to establish surrogate levels for substances without Standards for the protection of humans, although this would be little different from the traditional Factory Inspector type role for releases to air where occupational safety values have been widely used in the past. On the other hand it may be possible to argue that all the substances posing special risks to humans have Standards and for the other substances protection of the environment provides adequate protection to man. If this approach were adopted the BPEO assessment would use hazard indices which related to environmental effects only. Such an approach would need further in-depth thought but it may offer a more robust and defensible position than one in which either human and environmental risks are combined or one in which trade-offs would have to be made between effects on man and effects on the environment in determining BPEO.

The public perception of risks from prescribed processes tends to focus on health risks to humans rather than on wider environmental risks, especially in relation to the local community. Some standard setting frameworks (e.g. those used by WHO and US EPA) are moving in the direction of integrated exposure assessment. Similar approaches are currently being considered by HMIP for dealing with dioxins and in relation to the adaptation of the dose-commitment approach developed for exposure to radioactivity and toxic chemicals. These are attractive in that they provide an integrated risk assessment approach i.e. air, land, water and waste can all be treated together.

These integrated approaches, however, require a great deal of data on transfer coefficients if the assessments are to be realistic. They are also most convincing when applied to specific sites. These approaches should be developed further and their applicability to standard setting and BPEO assessment assessed in detail.

Standards for the environment are more difficult to set in an explicit way. The Dutch and US approaches set an objective for the protection of 95% of species with either a 95% (Dutch) or 50% (US) confidence limit. If this were used in the UK it could be

defended by reference to its use elsewhere. But in ecological terms 95% may be overly protective of ecosystem function if the system contains "redundancy" (Lawton 1994). A recent study of grassland ecosystems (Tilman *et al.* 1996) has shown that the loss of species diversity threatens ecosystem functioning and sustainability, although the data presented for the measures used (productivity and nutrient utilisation) indicated that the loss of 5 or 10% of species would probably not have had any measurable impact. This was not one of their conclusions but can be inferred by consideration of the data they presented.

On the other hand 95% protection may be politically inadequate if the 5% of species not protected were highly valued species such as game fish or top predators like sparrowhawk. In addition, there may be political pressure to maintain biodiversity, particularly at a more local level where rare species are present.

Some simple rules of thumb are probably needed. These could be built around key indicator species with an aim to protect these at a relatively high level. For example, that there should be no more than a 1% reduction in population as a result of exposure to the chemical concerned and that this should be ensured at a 95% level of confidence. Such an approach could be linked to the issues of Sustainable Development and Biodiversity by using key indicator species as objectives for EALs. The recently published report of the UK Steering Group on Biodiversity (HMSO 1995) contains lists of key species which could form a starting point for selection.

### Specify target and end point

This will be the best measurement that can be made in order to ensure that the given objective is met. The selection of target and end-point is fairly straightforward when dealing with human objectives. In dealing with the environment the target is often initially defined at an ecosystem level. In general, data are not available at this level of organisation and scientific argument and inference will be required to re-specify the target in terms of communities and then in terms of populations and ultimately in terms of numbers of individuals of a given species. This logical sequence will enable the target and end-point to be specified in terms of an effect concentration affecting n% of a population ($EC_n$) for a given species, exposure duration and toxicological end point.

Standards set for the protection of man already have a clear target. The end-point will however need further consideration and this will largely depend on the mode of toxic action of the chemical concerned. For example special attention will be needed if the chemical is a carcinogen. In general, however, the end-point for the protection of humans can be fairly readily identified.

The identification of target and end-point will depend on the way that the objective is formulated. If the objective is formulated, as in the example above, around key indicator species, the target is obvious and the end point can be identified by reference to that objective. The technical issue becomes one of identifying the controlling features in the population dynamics of the indicator species concerned and the ways in which the contaminant can affect these features. If the objective is phrased in more general terms such as that of ecosystem productivity, the identification of target and end-points becomes more difficult and an increased understanding of the relations

between ecosystem function, community structure and populations of species is required, before the species of concern and the appropriate end-point can be identified. Such analysis will however enable a suitable target and end-point to be nominated.

In either case a target and end-point will need to be identified and a confidence limit assigned, such that there is an acceptable level of risk associated with achieving the objective. Usually the output from this stage will be an effect concentration for a given organism and effect.

**Data collation and processing**

It is unlikely that experimental data will exist for the desired $EC_n$ value. In which case a logical path will need to be constructed linking the available data for the chemical concerned to the desired data. A number of extrapolation procedures may need to be employed in such a sequence involving, for example, acute to chronic, interspecies and effect extrapolations. These extrapolations are frequently part of conventional Standard setting procedures and the technique of "Analysis of Extrapolation Errors" (Suter 1993) can be used to ensure that uncertainties involved in such extrapolations are accounted for. Such extrapolations frequently have to rely on data for a range of chemicals other than that of interest and in such cases the more account that can be taken of mode of toxic action the better the reliability of the predictions.

Extrapolations are usually based on either a safety factor approach or one that uses statistical models. Whichever approach is taken to extrapolate results from available test data for a given substance to the data that are required for Standard setting, account has to be taken of differences in exposure time, interspecies sensitivities and different end-points of toxicity, within the dataset. When applied in a blind unthinking way neither the safety factor approach nor the statistical approach is reliable because neither has a firm basis in scientific understanding and experience and it is known that exceptions exist which negate the conclusions from the application of both. The most reliable estimate of the extrapolated value will come from an analysis which takes maximum account of the available information for the chemical, organism and end-point of concern. The application of safety factors frequently takes too little account of the range of data available, thus the same factor could be applied to the lowest data point whether two or twenty two toxicity values were available and regardless of the spread of values involved. On the other hand statistical approaches which aggregate all available data may obscure vital single value results. The advantage of the statistical approach is that the derivation is more transparent at least in concept and all measured data are taken into account. The disadvantage is that there are difficulties and large uncertainty bands if few data are available and the process of applying the statistics is less simple than the safety factor. However, if few data are available the safety factor approach is also obviously dubious. Both approaches can include elements of "expert judgement" which sometimes make decisions appear arbitrary.

*Worked examples using both approaches; trifluralin*

Trifluralin is a pesticide on the UK Red List of priority pollutants in the aquatic environment. An EQS of 0.1 $\mu g\ l^{-1}$ for the protection of freshwater life was established in 1990 as an annual average concentration (Jones 1990). This was derived by applying

a safety factor of 100 to the lowest credible adverse effect concentration; an acute LC50 of 0.01 mg $l^{-1}$ reported for rainbow trout (*Oncorhynchus mykiss*). In addition, a great deal of supporting information was available for other aquatic organisms. For example, 97% growth inhibition was reported for the alga, *Oedogonium cardiacum*, following exposure to a concentration of 0.02 mg $l^{-1}$ over a 30 day period. Algae are expected to be particularly sensitive, due to the herbicidal activity of trifluralin, although data for primary producers were limited to just a few studies, hence the reason for basing the Standard on reliable fish data. There was also a complete lifetime chronic study reported for fathead minnow (*Pimephales promelas*) in which a maximum tolerable concentration of between 0.002 and 0.005 mg $l^{-1}$ was observed. In another study, an acute LC50 of 0.9 mg $l^{-1}$ was reported for fathead minnow (*P.promelas*). The same study derived a chronic maximum tolerable concentration of between 0.002 and 0.007 mg $l^{-1}$ based on exposure over three generations.

Acute LC50 data are available for 29 different species; five fish, eight insects and the rest crustaceans. A statistical analysis of the data indicates that the lower 10-percentile of the distribution of values, assuming log normality, is 0.03 mg $l^{-1}$. A very similar non-parametric 10-percentile value can be calculated and this is 0.04 mg $l^{-1}$, with 90% confidence intervals of 0.01 to 0.06 mg $l^{-1}$. In other words, we can be 90% confident that if the concentration does not exceed 0.01 mg $l^{-1}$, 50% of populations will survive for 90% of aquatic species that are similar to the ones tested. To ensure that more than 99.9% of populations would survive we would need to divide the lowest 10-percentile concentration by the average dose response gradient or, if they were available, use LC0.1 values. The average ratio of LC50/LC0.1 is five for a large number of chemicals (Urban and Cook 1986 quoted in Suter 1993). Applying this factor to the lowest 10-percentile concentration, gives a value of 0.002 mg $l^{-1}$ which is very similar to the lower limit of both long term chronic studies.

Using probability distribution plots it appears as though the safety factor of 100 is roughly equivalent to an objective of protecting 99.9% of the organisms at a level of greater than 99.9%. This prediction is based on the assumption that the species distribution is log-normal and that the ratio of LC50 to LC1 is 5.

It is of course impossible to say which is the correct answer but the safety factor approach has given a result that is much lower than would normally be considered by application of statistical analysis of the available information.

**Real world comparison**

The values derived then need to be compared with any experience of the chemical in use and, if necessary, revisit the previous steps in the light of this experience.

### 5.3.4 An example of the approach

A specific example may help to clarify this approach. Imagine that the objective of an EAL is that there should be no more than a 1% probability that populations of key species in air, water or soil are affected. The particular organism representing this objective would depend on the mode of toxic action of the chemical (if it were

known). For example, if the substance were an insecticide consideration of the biodiversity targets may enable a particular dragon fly to be selected as the target species and the end point of concern may be survival of the larval form in water. Some target for a tolerable reduction in population would have to be determined, say 1%. It is unlikely that ecotoxicological data would be available for this species, although data for other crustaceans or insects may exist for the chemical of concern. It may also be possible to relate the ecotoxicological data for other chemicals between species. Such extrapolations would obviously have a measure of uncertainty about them and this could be represented in the risk level. Alternatively, it would have to be assumed that the data for other species were representative of the dragon fly target and once again uncertainty could be represented in a risk level. It would be necessary to relate the 1% probability of destroying the dragon fly population to the effect level on the nymph populations. A 1% probability at the adult population level may be reflected in a 10% increase failure of emergence in the nymph population. It follows that an EC10 for the nymph is the end point of concern.

Using the same example of the dragon fly, if the main route of exposure to another insecticide was via the atmosphere (e.g. as a result of high vapour pressure), the breeding adult stage may be more sensitive. It may then be possible to use ecotoxicity data for a representative organism (e.g. the house fly) to derive an appropriate standard for air.

## 5.4 Data availability

If this approach were to be followed for the derivation of EALs for all the substances of relevance to HMIP and for all media would enough data be available? The answer is undoubtedly no. However, if enough data are not available for the derivation of EALs how can Standards be derived? The problem of data availability is exactly the same in both cases.

In the absence of specific experimental data it is possible to develop approaches using structure activity relationships (SAR). Such approaches are obviously not 100% reliable but if data are not available they are the best alternative available. The other alternative is to make educated estimates even if this is cloaked in the guise of "expert judgement". Effect information for soils and for the impact on terrestrial organisms of atmospheric chemicals is sparse and these will probably be the biggest problem areas. There are, however, in addition to SARs possibilities of applying interspecies extrapolation in order to make predictions for species not tested from results for species with experimental data. This approach was first examined in detail by Kenega (1978) who pointed out that inter-species extrapolations across media, for example from fish to rats, can be used. This study has since been criticised (Peakall and Tucker 1985) but is an approach enabling decision making when no other information is available. The occupational Exposure Limits used for worker safety are derived at least partially on inhalation and/or dermal exposure in rats. Such data may also be of use in derivation of EALs in the absence of more directly relevant information.

## 5.5 Tolerable, intolerable and negligible

HMIP have placed environmental standards at the boundary between "tolerable" and "intolerable" in the proposed BPEO methodology and use the term "negligible" if concentrations are below a fraction of the standard. Standards themselves rarely recognise any intermediate concentration ranges and do not generally use terms like "tolerable" and "negligible".

The concepts involved in the use of these terms only have meaning when considered in relation to the objective i.e. tolerable etc, in relation to what? In the context of IPC the relevant consideration would probably be "harm". Harm can be considered as the movement of some attribute from some preferred state. It follows that intolerable harm could be considered to be a significant and probably permanent movement while tolerable may be an insignificant or transient movement. Negligible could be a movement which is without significance presumably because no change could be detected. As indicated in the previous paragraph these concepts do not currently play a part in Standard setting although some Agencies use Standards to define negligible values, the best example being the Dutch who define 1% of the Maximum Tolerable Concentration (MTC) as a level which is negligible. However, it should be noted that the Dutch use these negligible levels to define their long term quality Standards.

It is concluded that current Standards and their derivation procedures do not provide a good basis for assigning tolerable, intolerable or negligible levels of chemicals for use in BPEO assessments or for other purposes by HMIP.

# 6. CONCLUSIONS AND RECOMMENDATIONS

## 6.1 Conclusions

1. All relevant Standards for chemicals on the Chemical Release Inventory have been identified. Standards do not exist for the majority of them.

2. The most complete set of Standards relates to chemicals in the air, they are produced by HSE and are designed to protect worker safety. They are not set on a consistent toxicological basis and are not directly relevant to HMIPs responsibilities but are nonetheless useful as a basis for considering risks to humans.

3. Standards designed directly for environmental protection are relatively scarce. All are single media and most exist for water protection with a few for air and some for soil, mostly heavy metals, designed for particular regulations, e.g. sewage sludge application to land and guidance for contaminated land remediation. Critical loads consider multi media impacts but are solely concerned at present with releases of sulphur and nitrogen to the atmosphere.

4. Existing Standards are designed either to protect man or to protect "the environment". Sometimes, as in the case of the soil Standards for sludge, the most sensitive of these two is considered. In most cases, where man is the target, the objective of the Standard is clear, although it is often not possible to be certain about the level of risk implied by the particular value selected particularly for non-carcinogens. When "the environment" is the objective, terms like "the protection of ecosystem structure and function" are sometimes used but our understanding of these concepts is insufficient for them to be put into a tangible, measurable form. When alternative tangible objectives are set such as "the protection of 95% of the species with a 95% confidence limit" as adopted by the US EPA and Dutch authorities there is a clear measurement point, but the true risk to the environment is unknown and probably quite different in different specific cases.

5. Analysis of selected examples of Standards indicates that it is not possible to retrospectively evaluate the degree of risk implied in any reliable way. In part, this is associated with the lack of clarity of the objectives and the fundamental ignorance of the responses of the organisms and systems involved, and in part is due to the widespread use of "safety factors" which introduce reductions in risk levels that are not quantifiable with any confidence. An example of one approach which could be taken to quantify the implicit risk is given in the text but no great confidence should be placed on the results that could come from such retrospective analyses.

6. Consideration of the terms "tolerable", "intolerable" and "negligible" as used by HMIP in their proposed BPEO methodology and the procedures used for deriving Standards, leads to the conclusion that the objective in Standard setting

is to establish a level below which no adverse effects are expected. This is closer to the boundary between "tolerable" and "negligible" rather than between "intolerable" and "tolerable" as currently used by HMIP.

7. Options are identified for bringing more consistency into Standard setting particularly in relation to multi media standards. Three options are considered but only one is recommended for further attention. An explicitly risk based procedure is proposed and outlined. The first step needs to be a clear statement of the objective. For use by HMIP, it would in our view be highly desirable to have a clear distinction between Standards for the protection of man and those for the protection of the environment.

8. There are three main uses that HMIP makes of Standards and there is a need for improved access to Standards in relation to these uses. There is however a difference between the purpose of Standards and the use that HMIP has for EALs in BPEO assessments. This difference is fundamental and it is concluded that HMIP should consider making the difference more absolute. In this case Standards would be set by others and used by HMIP in the same way as currently, but for BPEO assessment only EALs would be used. The EALs would be set using a risk based approach with a specific objective of equalising impacts on all media. An approach for doing this is outlined in the text. It would need to adopt a great deal of pragmatism since the underlying data will in many cases be absent as is the fundamental understanding of ecosystem functioning. Nevertheless, this is considered a viable approach which offers many advantages to HMIP.

9. HMIP has three basic options in setting EALs for different targets (i.e. man and the environment). It can set EALs, as presently proposed, based on the most sensitive. This runs the risk of the accusation of comparing apples with pears and further carries an implicit assessment of relative risks in assessing the BPEO. This implicit assessment could subsequently be unravelled and exposed by pressure groups. Alternatively, HMIP could have a separate set of values for man and the environment. This would mean parallel hazard index assessments and a final trade off in some form or another of the two values. Or finally HMIP could consider Standards for humans as the boundary between tolerable and negligible and not involve human effect assessment as part of the BPEO comparison exercise. If necessary this may mean establishing values for some chemicals with equivalent risk levels to those for existing Standards. This is similar to the traditional activity of Alkali and other Inspectors

10. If EALs were to be set in the way proposed it is recommended that effects on man and effects on the environment are treated separately. Consideration should also be given to treating effects on humans as though there is no "tolerable" concentration range i.e. that all discharges should meet an acceptable level of risk and that human exposure is not a part of the BPEO assessment that considers and ranks different process options.

11. HMIP personnel need access to Standards to assist them in a variety of their functions. While the specific needs are different there are many elements in common and these needs could be best met by having a single database available

which could ensure consistency. Such a database would, however, need to be designed to meet user needs, to fit into HMIPs other database plans such as SIS and to be updated regularly. It would also have increased credibility if the data used were widely available outside HMIP. Since commercial databases already exist covering much of the relevant information, careful thought would be required before public funds were used to create a similar system.

## 6.2 Recommendations

1. The option of creating EALs for sole use in BPEO assessments should be carefully considered by HMIP and further work initiated on a feasibility study of the procedures and their implementation.

2. More detailed consideration should be given by HMIP to the proposal that human and environmental assessments should be undertaken separately in the BPEO framework and that the process option comparison is based primarily on the environmental evaluation. This would be justified by reference to a provision that all discharges should meet Standards which imply a "negligible" effect on humans.

3. The fundamental difference between elements and organic chemicals needs to be recognised in Standard setting and implementation. The implications of these differences needs to be considered in more depth. This is an issue that could be presented to the Royal Commission on Environmental Pollution for consideration in their current study.

4. The development of a standards database is seen as desirable to ensure consistency of use within HMIP. However, because of the development of the Substance Information System (SIS) it is recommended that information on standards is entered into this system. To facilitate updating and quality assurance it is recommended that standards should be entered by organisation rather than by substance, on a standard pro-forma, agreed with the SIM project Manager.

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# APPENDIX A REVIEW OF STANDARD SETTING PROCEDURES FOR WATER

## A1 SUMMARY OF APPROACHES AND IMPLIED RISK

Since in relation to water, HMIP are primarily concerned with the protection of aquatic life following discharge to surface waters, Standards for other water uses are not referred to extensively in this report. However, mention is made of WHO drinking water guidelines to illustrate how risks to human health are assessed.

The objective of Standards for the protection of aquatic life is usually to protect structure, function and long-term health of the whole ecosystem. The derivation of Standards generally involves extrapolation from a limited number of laboratory toxicity data (e.g. acute LC50, chronic NOEC) to a 'safe' environmental concentration. The following aspects are considered in the extrapolation process:

- interspecies variability;
- intraspecies variability;
- extrapolation to no-effects concentrations in the environment from laboratory-based acute and chronic data.

Extrapolation methodologies generally apply two different approaches in the derivation of Standards:

a) the use of empirical safety factors;

b) the use of statistical models.

### A1.1 The use of safety factors

A number of the methodologies reviewed use safety factors for the derivation of environmental Standards. The factors are applied to the lowest effect/no-effect concentration reported in the laboratory to extrapolate to a no-effect concentration in the field. The laboratory data usually consist of an L(E)C50 or a NOEC. The former has the advantage in that it is interpolated from a dose-response plot, whereas the latter is simply the highest concentration tested at which effects were not statistically different to those observed in the control. There are a number of advantages associated with this approach. These are:

- they are simple to apply (i.e. do not involve complex statistical calculations);

- they allow expert scientific judgement to influence the derivation process (safety factors may be adjusted on the basis of validated scientific assessment);
- they aim to protect all species;
- they are transparent and the derivation can therefore be easily documented;
- justification of the Standards can be easily assessed.

This approach assumes that protecting ecosystem structure (i.e. safeguarding all species) will protect ecosystem function. However, this relationship is poorly understood and the approach may lead to the derivation of over-protective Standards if, for example, loss of a certain fraction of the most sensitive organisms has no effect on ecosystem function. This thinking forms the basis of the statistically derived Standards discussed later.

### A1.1.1 Level of risk implicit in the safety factor approach

Safety factors are chiefly applied to account for the uncertainty in extrapolating from effect/no effect concentrations on single species in the laboratory to no-effect concentrations for complex aquatic communities in the field, and do not in themselves precisely quantify risk. However, a certain level of risk is associated with the expression of these Standards, if only qualitative. For instance, if studies in the field indicate that toxicity is lower than would be expected from laboratory studies, the safety factor normally applied to the laboratory data may be reduced, thus recognising the reduced risk of exposure under field conditions. Moreover, the application of a safety factor to the most sensitive life stages of the most sensitive species is in itself a recognition of the increased risk of toxic effects to these organisms, as is the application of an additional safety factor to minimise the risk of exposure to substances that may accumulate in tissues of sensitive species to levels equivalent to toxic body burdens.

A further recognition of risk is associated with the expression of safety factor derived EQSs in the UK. For instance, a maximum allowable concentration (MAC) for the protection of aquatic life against the adverse effects of short-term episodic inputs (e.g. spray-drift from agriculturally applied pesticides) is usually set around an order of magnitude higher than the annual average concentration which aims to protect aquatic organisms exposed to continuous inputs of substances over the long-term. This expression recognises that acute effects at higher concentrations following short-term episodic exposures are of greatest concern and that risk of effects in the long-term are lower than if organisms were exposed continuously. In addition, the expression of EQSs as 'dissolved' concentrations (rather than 'total') for substances that readily adsorb to suspended solids and sediments (e.g. some pesticides and metals) recognises the reduced risk of exposure to these chemicals under field conditions, as compared to studies conducted in the laboratory where bioavailability in the absence of suspended solids may be higher. Similarly, the expression of EQSs at different hardness bands or pH recognises that the risk of toxic effects can vary for certain substances (e.g. metals)

depending on speciation, which is, in turn, dependent on natural water quality parameters.

It may be possible to associate a 'quantitative' expression of risk with each safety factor applied in the Standard setting procedure. For example, an acute LC50 for fish is in itself an expression of risk, in that at a specific concentration 50% of individuals in a test population are expected to die in a given exposure period. Therefore, if the shape of the dose-response curve is known, it may be possible to extrapolate back to the acceptable risk level (e.g. one fish mortality per n individuals) associated with the derived Standard, following application of the safety factor to the acute LC50. Such expressions of risk may help to provide a common currency for comparing relative risks of polluting substances across media.

For non-carcinogenic chemicals, the derivation of WHO drinking water guidelines assess risk at a qualitative level, where only a fraction of the Tolerable Daily Intake (TDI) based on mammalian toxicity data is allocated to drinking water to account for exposure via other routes (e.g. air, food residues, etc). Furthermore, lower values may be set for infants for some substances thus recognising the increased risk of toxic effects to this sensitive group of the population. The TDI is equivalent to a concentration that can be ingested every day for life without appreciable risks to human health. It is expressed on a body-weight basis.

## A1.2 The use of statistical models

Statistical models to extrapolate from laboratory data to Standards for the protection of aquatic life are used by the US EPA for the derivation of National Criteria and the Dutch RIVM for the derivation of Maximum Tolerable Concentrations (MTC) and Negligible Concentrations (NCH). In addition, mathematical models are used to assess the risks of cancer to humans of drinking water containing carcinogenic substances.

Models for the protection of aquatic life have the advantage that they utilise all available data. However, they have some limitations:

- models generally require a large data-set;
- models only work well when the data obey a certain distribution (e.g. log triangular (US EPA), log-logistic (Dutch RIVM));
- Standards derived using models are not transparent.

The outcome of statistical models is a concentration that aims to protect a percentile of organisms (e.g. 95%). These values assume that protecting 95% of species protects the ecosystem as a whole. If this assumption holds true, statistical models could negate the use of potentially over-precautionary safety factors. However, it is not possible to assert this with confidence given the uncertainties in predicting the implications for the ecosystem of loss of a group of species in terms of structure and function. Indeed, it is clear that US EPA and RIVM recognise these uncertainties by the fact that a margin of safety is applied to the outcome of the statistical models. Moreover, doubts are often raised over the potential differences in sensitivity of similar species under field and

laboratory conditions (OECD 1989, Health Council of the Netherlands 1989) thus challenging the validity of the extrapolation.

### A1.2.1 Level of risk implicit in the statistical approach

The degree to which risk is assessed in statistical extrapolation procedures would appear to have more of a 'quantitative' basis than in the safety factor approach. This is because the assumption that 95% of species are protected at a specific concentration, implies that there is a 5% probability that the more sensitive species in an ecosystem may be adversely affected (although not to the detriment of long-term health of the ecosystem as a whole). However, this relationship is poorly understood, appears to have no real scientific basis and the protection percentile chosen is apparently arbitrary. Therefore, although the statistical approach appears to have more of a risk basis than the safety factor approach, the 'true' risk to individuals in an ecosystem is not quantified to any precision by either method.

A qualitative expression of risk is associated with the practical application of the statistically derived RIVM Standards. RIVM define a "Negligible Concentration" (NC) as having "negligible risk" to the environment. However, since the NC is derived simply by dividing the Maximum Tolerable Concentration (MTC) by 100, the basis of the NC is apparently arbitrary. RIVM set their NCs and MTCs as 'target' and 'limit' values, respectively. In between these two values and above the MTC are set 'Guide' and 'Intervention' values, respectively. Thus, the setting of four different Standards recognises different levels of risk to the environment and the associated degree of risk management that is necessary at each level.

For genotoxic carcinogenic substances in drinking water, WHO set guidelines based on mathematical models that express risk quantitatively. The values are presented as the concentration in drinking-water associated with an estimated excess lifetime cancer risk of $10^{-5}$. This risk equates to one additional cancer case per 100 000 of the population ingesting drinking water containing the substance at the guideline value for 70 years.

## A2 CASE STUDIES

### A2.1 Case Studies 1 and 2: The 'Dangerous Substances Directive' (76/464/EEC)

#### Introduction

This was the first EU Directive (CEC 1976) to clearly lay out a regulatory framework for the discharge of chemical substances to inland and coastal waters. Its full title is "Council Directive of 4 May 1976 on pollution caused by certain substances discharged into the aquatic environment of the Community" and should not be confused with directive 67/548/EEC, which controls the use of dangerous substances by means of labelling and notification, and is often referred to in the same abbreviated way.

Two alternative approaches to control are provided in the directive; The Limit Value (LV) and Environmental Quality Standard (EQS) approach. The former consists of adopting fixed uniform emission limits that are based on best technical means for reducing discharges, taking into account the economic viability of those means, while the latter (broadly adopted in the UK) involves the use of concentration limits (EQSs) that should not be exceeded in receiving waters if the use for which that water body is intended is not to be compromised. In UK parlance EQSs are set to protect different Environmental Quality Objectives (EQOs), or in other words different uses, such as protection of aquatic life, abstraction to potable supply, irrigation of crops, etc. This review will assess the use of EQSs to protect aquatic life. In practice the UK adopts both approaches through the concept of IPC in its assessment of BATNEEC for prescribed processes.

Chemical substances covered by the Dangerous Substances Directive are selected on the basis of their toxicity, persistence and bioaccumulation potential. The substances are divided into two categories. The first comprises those substances considered to be most harmful by which pollution must be eliminated, while the second comprises less harmful substances (although still deleterious to the aquatic environment) by which pollution must be reduced. The former category is referred to as List I and the latter as List II. In broad terms, List I substances are controlled at the EU level, with Standards for discharge or environmental quality that must be adopted by all member states, while List II substances are controlled at national level. The procedures used to derive Standards for each category are discussed in detail in the following sections. EQSs set in the UK for List II substances shall be discussed first as there is a far greater amount of information available than for the setting of Standards for List I substances at the EU level.

### A2.1.1 Case Study 1: Derivation of EQSs in the UK for List II Substances

**Background**

To date, EQSs for List II substances have been derived by WRc for the Department of the Environment (DoE) who then adopt the Standards into UK legislation following a peer review by interested parties, such as industrial representatives and regulatory authorities.

Essentially, EQSs aim to protect aquatic life against the adverse effects of both point and diffuse sources of chemical input to the aquatic environment. The basic assumptions underlying the EQS process are that:

- there is a certain acceptable concentration of a pollutant which does not cause adverse effects to aquatic organisms;
- the aquatic environment therefore has a certain capacity to accommodate pollutants;
- this capacity can be quantified.

In the UK, EQSs are used at a site-specific level to set effluent discharge consents and to control/prosecute following pollution incidents, and at a non-site specific level in the control of uses of certain substances to prevent diffuse inputs to surface waters (e.g. agricultural pesticides).

## Procedure

The UK approach for setting EQSs is a pragmatic one based on a detailed scientific assessment of all the data available for the substance. In the derivation process, laboratory and field toxicity data, as well as the sources and entry of the substance to the environment, its environmental fate and behaviour and bioaccumulation potential are considered. This process can be summarised as follows:

a) Identification of potential sources for input to the aquatic environment;

b) Determination of environmental fate and behaviour;

c) Identification of the lowest credible adverse effects or highest no-effects concentration for the most sensitive aquatic organisms;

d) Extrapolation to a "safe" concentration under field conditions (i.e. establish preliminary EQS);

e) Validation of preliminary EQS by comparison with field studies and monitoring data;

f) Repeat of stages (a) to (e) if there are discrepancies;

g) Establish EQS.

Essentially steps c) and d) form the main part of the EQS derivation procedure.

### Identification of the lowest credible adverse effects or highest no-effects concentration

In general, confidence in an EQS increases with the size, reliability and relevance of the toxicological dataset from which it is derived. Therefore, when deriving an EQS all available toxicity data are collated and critically analysed in order to assess reliability and relevance to the aquatic environment and to ultimately determine the lowest credible concentration having a significant effect or the highest concentration having no effect.

A considerable amount of research has been conducted with regards to what constitutes a minimum dataset in order to do this. Studies conducted on distribution of species sensitivity (US EPA 1984 and OECD 1992) suggest that sensitivities of aquatic organisms follow a log normal distribution pattern and that only sets of eight or more data are required to represent "species sensitivity" (i.e. the majority of species, not necessarily the most sensitive ones). Therefore, in deriving EQSs a minimum of eight toxicity values is required, ideally a mixture of acute and chronic data on species

(preferably temperate) classified into the following trophic groups; algae, crustaceans, insects (freshwater only), non-arthropods (e.g. molluscs) and fish. In addition, if the substance under review has a well known target group of organisms (e.g. insecticides) these must be well represented in the dataset (preferably at least two distinct species). Moreover, if water quality parameters are known to affect toxicity a suitable number of water conditions need to have been tested.

Toxicity data included in the minimum data-set should meet certain quality criteria. The quality of data is assessed against Standardised test procedures and classified as primary or secondary data depending on how closely these Standardised procedures are followed. While the derivation of an EQS requires the use of primary data, secondary data may be used to support the derivation. If data are not available for some of the taxonomic groups mentioned above (either primary or secondary) a "tentative EQS" is proposed with the provision that it should be reviewed when more suitable data become available.

**Extrapolation to a "safe" concentration under field conditions**

Toxicity data reported in the literature are obtained mainly from laboratory studies conducted on single species. In order to extrapolate from the most credible lowest effect/highest no-effect concentration, as identified in the previous stage of the derivation procedure, a "safety factor" is applied to account for:

a) uncertainty in extrapolating from acute effect concentrations to chronic effect concentrations;

b) uncertainty in extrapolating toxicity data obtained under artificial, controlled laboratory conditions to toxicity under variable environmental conditions;

c) uncertainty in extrapolating from effect concentrations on a few test species exposed in isolation to a no-effect concentration intended to protect complex aquatic ecosystems comprising very biologically diverse communities;

d) uncertainty regarding whether Standard test species adequately represent the most sensitive organisms, particularly for biologically active compounds such as insecticides.

This approach assumes that protecting ecosystem structure (i.e. safeguarding all individuals) will protect ecosystem function.

The degree of uncertainty inherent in the derivation procedure is reflected in the size of the safety factor used to set the EQS. In the UK, safety factors of 100, 10 and 1 are applied to acute, chronic and field data, respectively, to derive EQSs for List II substances. These are generally based on safety factors developed by the OECD (OECD 1991). These factors are only guidelines and can be changed if there is scientific justification for doing so. For instance, the safety factor of 100 incorporates a factor of 10 to extrapolate from acute effect concentrations to chronic effect concentrations. Similarly there is a factor 10 to go from chronic effect concentrations to no-effect concentrations in the field. However, if the dataset indicates that ratios

between acute and chronic or chronic and field effect/no-effect concentrations are either greater or lower than 10, the extrapolation factors can be adjusted accordingly.

In addition to the above, a safety factor of 10 is usually applied if the substance has a high bioaccumulation potential and is persistent in the tissues of biota. This gives an added level of protection to prevent the concentration of chemicals accumulating to a level equivalent to the toxic body burden in the tissues of aquatic organisms.

The above safety factors can be scientifically justified, at least in part, as follows.

a) Acute:chronic ratios

In comparing acute LC50/EC50 values with chronic Lowest-Observed Effect Concentrations (LOEC) and NOEC values obtained from otherwise similar studies (i.e. same species, same test conditions), the following appear to hold true (US EPA 1984):

- The acute to chronic ratio is within two orders of magnitude for 95% of substances
- The acute to chronic ratio is within an order of magnitude for 50% of substances

In addition, ECETOC (1993) examined the relationship between acute and chronic toxicity data for 368 substances and 122 aquatic species in order to provide a scientific basis for the use of safety factors. The researchers found that median ratios between acute EC50 and chronic NOEC data ranged from 3.6 to 28 and that a factor of 28 could therefore be considered suitable for predicting chronic data on the basis of acute data. This is somewhat less conservative than the earlier ECETOC value of 40 which applied to 90% of substances.

Therefore, for an "average" substance a factor of 10 applied to the lowest acute value should give a reasonable prediction of the lowest chronic effect or no-effect concentration.

b) Variability and uncertainty

A factor of 10 is considered appropriate to extrapolate from a chronic effect/no-effect concentration to a "safe" concentration in the field. This is in part to account for the possible existence of species more sensitive than those on which the EQS is based. The US EPA (US EPA 1984) have investigated the difference in sensitivity between species exposed to a range of chemicals by comparing acute LC50s. Variability was found to be high, but in general a factor of 2.4 to 48.9 applied to a single "typical" LC50 encompassed 50% to 95% of the lower LC50s for that chemical, depending on the range of species investigated. Konemann (1984) conducted a similar investigation and found that relative susceptibilities ranged from 1.0 to 6.3 for a wide range of organisms (from bacteria up to amphibians). The results obtained in these studies suggest that a factor of 10 appears to be appropriate in allowing for inter-species variability.

ECETOC (1993) report that data are too limited to analyse chronic NOEC to ecosystem NOEC ratios (only two useable study pairs for two chemicals are available). However, in an earlier study ECETOC suggested a tentative factor of 5 for 90% of substances to extrapolate from chronic NOEC data to an ecosystem NOEC value.

### Expression of EQSs

EQSs can be expressed as either a Maximum Allowable Concentration (100-percentile), a 95-percentile concentration (5% exceedance is tolerated) or a 50-percentile concentration (annual average concentration). However, EQSs for the protection of aquatic life are usually set in two parts; a Maximum Allowable Concentration (MAC) designed to protect against short-term exposure and an annual average concentration designed to permit the survival of healthy aquatic communities during long-term exposure. The MAC is of greatest use in protecting against the adverse effects of episodic events (e.g. spray-drift from agricultural applications of pesticides), whereas the annual average is more suitable for the protection of aquatic communities against the effects of continuos discharges (e.g. in industrial effluents).

Depending on the nature of the substance (e.g. its physico-chemical properties, fate and behaviour in the environment), EQSs are expressed either as 'total' or 'dissolved' concentrations. The latter expression accounts for the reduced bioavailability of certain substances when adsorbed to suspended solids and sediments.

The expression of EQSs as either MACs or annual averages recognises the difference in risk of toxic effects occurring following short and long-term exposure to chemicals. Similarly, the distinction between total and dissolved concentrations recognises that for certain chemicals risk of exposure under field conditions is reduced as a result of reduced bioavailability.

## Worked examples

### Trifluralin

An EQS expressed as annual average of 0.1 $\mu g\ l^{-1}$ has been proposed for the Red List herbicide trifluralin (WRc 1990) by the application of a safety factor of 100 to a 96 hour LC50 reported for rainbow trout in the laboratory. A corresponding MAC of 1.0 $\mu g\ l^{-1}$ has been set by the application of a factor of 10 to the same data. These values are expressed as dissolved concentrations to account for the non-bioavailability of this compound when adsorbed to suspended solids and sediments. However, a MAC of 20.0 $\mu g\ l^{-1}$ has also been proposed for 'total' trifluralin based on a laboratory study that exposed fish in the presence of suspended solids.

### Fenitrothion

An EQS expressed as annual average of 0.01 $\mu g\ l^{-1}$ has been proposed for the Red List insecticide fenitrothion (WRc 1991) by the application of a safety factor of 100 to a range of acute LC50s obtained for crustaceans and insects in the laboratory. A corresponding MAC of 0.25 $\mu g\ l^{-1}$ has been set by the application of a factor of five to

the highest NOEC for drift of invertebrates exposed under field conditions. Scientific judgement has been exercised here; the factor of five was considered necessary to account for the possible existence of more sensitive species in receiving water bodies. These values are expressed as dissolved concentrations to account for the non-bioavailability of this compound when adsorbed to suspended solids and sediments.

**Chromium**

Revised EQSs expressed as dissolved annual averages of 2.0, 10.0 and 20.0 $\mu g\ l^{-1}$ have been proposed for the List II metal chromium (WRc 1994) in waters of hardness <50, 50-150 and >150 mg Ca $CO_3\ l^{-1}$, respectively. Similar factors were used as above to derive these Standards. Toxic effects are mainly attributed to the Cr ions (III and VI oxidation states). Since speciation of the metal depends on water hardness, the differing EQSs for different hardness bandings reflect the fact that toxicity varies according to ambient water chemistry. Moreover, the EQSs are expressed as dissolved concentrations to account for the non-bioavailability when adsorbed to suspended solids and sediments.

### A2.1.2 Case Study 2: Derivation of EQSs for I Substances at the EU level

**Procedure**

The formal procedure by which EQSs (EQOs in EU parlance) are derived for the protection of aquatic life have not been published in detail. However, the general approach and some examples of safety factors are summarised by Bro-Rasmussen *et al* (1994).

The approach adopted appears to be essentially the same as that employed in the UK for deriving EQSs for List II substances. The Commission (DG XI, Directorate-General for Environment, Nuclear Safety and Civil Protection) selects suitable contractors, who collate data from published and other sources with regards to sources of input, physico-chemical properties, fate and behaviour in the environment and aquatic/mammalian toxicity of the substance under review. As in the UK, consideration is given to data quality and datasets for target groups of organisms. The safety factors applied are similar to those used in the UK and reflect acute and chronic exposure as well as the quantity/quality of the data available. One difference is that there does not appear to be a factor of 1 available for application to well conducted, representative field studies.

The EU employs the following safety factors:

- *1000 to the lower end of acute L(E)C50 range,* when the data available are few or the range of organisms is narrow
- *100 to the lower end of acute L(E)C50 range,* when there is an extensive dataset for a wide range of species representing all trophic levels, *or* to the lower end of apparent chronic NOEC data when such data are limited.

- *10 the lower end of (apparent) chronic NOEC data,* when there is an extensive dataset for a wide range of species representing all trophic levels

In addition to the above, most EU Directives for dangerous substances also included a 'standstill provision' which states that total concentration must not increase significantly with time in sediments, shellfish and fish. This provision recognises the increased risk of toxic effects following accumulation to toxic body burdens in the tissues of biota.

**Worked examples**

Full details of the derivation procedure employed by the EU is not available. However, the following examples are reported in Bro-Rasmussen *et al* (1994).

**Hexachlorobutadiene**

An EQS expressed as a 'total' annual average of 0.1 $\mu g\ l^{-1}$ has been adopted into EU legislation for the List I organic substance, hexachlorobutadiene. This Standard was derived by applying a safety factor of 100 to a range of chronic toxicity data and also allowed for bioaccumulation potential.

**Chloronitrobenzenes**

An EQS of 1.0 $\mu g\ l^{-1}$ has been proposed to the EU for the priority List I organic substances, chloronitrobenzenes (*o*-, *m*- and *p*-). This Standard was derived by applying a safety factor of 1000 to the lower end of acute LC50 values. The factor also takes into account persistence and general paucity of data.

### A2.1.3 Case Study 3: Derivation of EQSs for substances of concern to NRA

EQSs are also derived in the UK for substances that are of specific concern to the National Rivers Authority (NRA, e.g. sheep dip chemicals) but which have not yet been prioritised for EQS development by DoE or at the EU level. The method by which they are derived is identical to that adopted for deriving EQSs for adoption into UK legislation as List II substances (see Section A1.1.1). WRc has derived EQSs for NRA since its formation in 1989. The EQSs set for NRA are not statutory, but are used to set legally-binding discharges consents.

# A3 OTHER PROCEDURES

## A3.1 Canadian procedures for setting environmental Standards

The Canadian approach to setting environmental Standards for the protection of freshwater life is very similar to that adopted in the UK (CCME 1991). Water Quality Guidelines are established as maximum concentrations that should not be exceeded at any time if aquatic life is to be protected in the long-term.

Data are collated on physico-chemical properties, reported environmental concentrations, fate and behaviour in the environment and acute/chronic toxicity. As in the UK, a minimum toxicity dataset must be met both in terms of quantity and quality of data. A safety factor (10, 50 or 100) is then applied to the Lowest Observed Effects Level (LOEL) obtained in a chronic study or the effect level (LC50 or EC50) from an acute study to derive the Guideline. The size of the factor applied depends on the type of toxicity data used to set the Standard.

## A3.2 US procedures for setting environmental Standards

The US EPA essentially utilises two different approaches to setting environmental Standards for the protection of freshwater life. The derivation of National Water Quality Criteria makes use of statistical models to extrapolate from effects in the laboratory to no effects in the field (US EPA 1985), while the setting of Concern Levels adopts the use of safety factors as in the UK and Canada.

### A3.2.1 National Water Quality Criteria

The National Water Quality Criteria are comprised of two different Standards, Criterion Maximum Concentrations (CMC) based on acute toxicity data providing protection for short-term exposure, and a Criterion Continuous Concentration (CCC) taking account of chronic exposure, aquatic plant toxicity, bioaccumulation (including the protection of humans eating edible aquatic life), and any other data of biological importance, providing protection for long-term exposure.

The extrapolation model used in the derivation of National Water Quality Criteria requires acute and chronic toxicity data for at least one species from eight different families, although acute-chronic ratios (ACR's) from a minimum of three families may be used to estimate chronic toxicities. The method assumes that these data will obey a log-triangular distribution pattern.

The geometric mean of acute and chronic data for each species and each genera are calculated and fed into a computer model which calculates the cumulative probability for each generic mean. The four generic mean values that have cumulative probabilities closest to 0.05 are used to calculate the Standard. The outcome is a statistically derived concentration (known as the Final Acute or Final Chronic value) that aims to protect 95% of aquatic species (P = 0.05). The Criterion Maximum Concentration is

defined as one half of the Final Acute Value, while the Criterion Continuous Concentration is defined as the lowest Final Chronic Value, Final Plant Value or Final Residue Value. The latter two values are derived for the protection of important aquatic plants and to prevent the exceedence of action levels in the tissues of commercially important aquatic species.

### A3.2.2 Concern levels

Concern levels are used mainly in the preliminary assessment of substances and where data are insufficient to employ the statistical method outlined above. They provide an indication to regulators of the likely 'safe' concentration of a substance discharged to the aquatic environment. The protocol for deriving US Concern Levels was also developed by the US EPA (US EPA 1984).

No minimum data-set or formal quality assessment is specified for the derivation of Concern Levels. They may be derived from either:

- the lowest chronic effect concentration;
- the lowest LC50 concentration from many acute tests; or
- one LC50 from an acute test or an LC50 estimated by Quantitative Structure Activity Relationship (QSAR).

The uncertainty associated with the extrapolation of laboratory based data to field situations is accounted for by the use of safety factors very similar to those used in the UK. These are as follows:

| Critical data | Safety factor |
|---|---|
| Field effect level | 1 |
| Lowest chronic effect concentration | 10 |
| Lowest acute effect concentration (from many tests) | 100 |
| One acute toxicity value | 1000 |
| Toxicity estimated by QSAR | 1000 |

## A3.3 Dutch procedures for setting environmental standards

### A3.3.1 Background

The National Institute for Public Health and Environmental Protection (RIVM) on behalf of the Ministry of Housing, Physical Planning and Environmental Protection (VROM) have developed a system for determining "Maximum Tolerable Concentrations" (MTC) and "Negligible Concentrations" (NCH) for soil, groundwater, surface water, sediments and air as a means of setting integrated Standards that follow a consistent approach (Van de Meent *et al* 1990, Sloof 1992). If insufficient data are available to derive these Standards a simplified methodology is used to derive Concern Levels for a preliminary effects assessment. This methodology is a modification of the US EPA protocol for deriving concern levels (US EPA 1984) and uses similar safety factors (see Section A1.2).

In response to the National Policy Document for Water Management 1989-1994, the Institute for Inland Water Management and Waste Water Treatment (RIZA) has derived numerical Environmental Quality Objectives (EQOs) for surface waters and sediment using a different approach. The EQOs are intended as intermediate values between the Maximum Tolerable Concentration (MTC) and Negligible Concentration (NCH) derived by RIVM and are considered as national minimum Standards which are to be met by the year 2000.

In the Netherlands, the above Standards are referred to as 'risk limits', with MTCs, NCs and EQOs defined as 'Limit Values', 'Target Values' and 'Guidance Values', respectively. In addition, an 'Intervention Value' is defined as a concentration set somewhat higher than the MTC which, if reached, should trigger immediate remediation measures.

Since the Netherlands recently decided to adopt the methodology developed by RIVM as the single approach used to derive Environmental Quality Objectives (Ministry of Housing, Spatial Planning and Environment 1994), only the RIVM methodology has been considered in this review.

### A3.3.2 Procedure

MTCs are defined as the concentration at which 95% of the species in an ecosystem are fully protected, while NCs are defined simply as 1% of the MTC. MTCs are extrapolated from single-species toxicity data using a statistical model which assumes a log-logistic species distribution. Effects through the aquatic food chain (secondary poisoning) are also taken into account in the derivation of MTCs for water. If an MTC derived for secondary poisoning is found to be lower than the MTC based on ecotoxicological data, it is adopted as the final water MTC.

N.B. RIVM believe that the same basic method underlying the derivation of the MTC for water can also be applied to deriving MTCs for organisms in other media (i.e. atmospheric and terrestrial compartments). However, given the absence/limited

availability of data from toxicity studies that specifically expose relevant organisms in air and soil, RIVM propose that MTCs for these media can be derived by the application of equilibrium partitioning to the water Standard.

The derivation of MTCs requires chronic toxicity data for four or more species of different taxonomic groups for a particular compartment of the aquatic ecosystem (e.g. aquatic organisms or predators of aquatic life). Chronic NOECs used in the derivation process may be estimated from acute toxicity data (acute LC50s or EC50s) using reliable acute-chronic ratios for the same substance with another test species. This procedure is only applied for the extrapolation between different fish species, species of the same genus, or other groups if supported by sound data.

The MTC for a substance is determined from single species data using a statistical model which assumes a log-logistic distribution of species sensitivities. The model used in this methodology is that of Aldenberg and Slob (1991), which is based on earlier approaches by Kooijman (1987) and van Straalen and Denneman (1989).

The first stage in the derivation process, however, is to assess whether the reported chronic NOECs follow the log-logistic distribution curve. The "goodness-of-fit" for NOECs is tested using an Empirical Distribution Function Test (Aldenberg and Slob 1991). This test presents the significance level at which the log-logistic distribution is rejected. If it is rejected at a significance level of >1% it is unlikely that the species sensitivities are log-logistically distributed. In such cases, the mode of action of a substance is then evaluated in order to identify outliers in the toxicity data-set. If justifiable, outliers are removed from the input data-set and the extrapolation model of Aldenberg and Slob (1991) is followed. If the available NOECs are not log-logistically distributed and there are no reasons for the omission of outliers the model is still run, although the results are presented together with the outcome of a preliminary effects assessment based on the derivation of a concern level using the safety factor approach.

The extrapolation model estimates the MTC defined as the concentration at which the NOEC for 95% of the species within the ecosystem is not exceeded on the basis of the distribution of experimental NOECs. In other words, the model estimates a critical concentration, above which 5% of species may be adversely affected (P = 0.05). This concentration is chosen such that it presents the median estimate of the 95% protection level (lower 50% confidence limit). An extrapolation factor is associated with this figure to allow for uncertainty in the procedure, This factor depends on the size of the dataset used to create the log-logistic distribution and is defined as a function of the Standard deviation of the NOECs, the fraction of species not reported, the number of tested species and the probability of over-estimating the 95-percentile output from the model.

## A3.4 WHO procedures for setting drinking water guidelines

In 1993, the World Health Organisation (WHO) revised their drinking water guideline values which had been previously published in 1984. The recommended guideline values along with an explanation of how they were derived is published in detail in the 1993 'Guidelines for drinking-water quality', 2nd edition, Volume 1

(Recommendations). In summary, WHO used two approaches for deriving their drinking water guideline values and these are described below in broad-terms.

For non-carcinogenic chemicals or those chemicals which have carcinogenic potential but do not react directly with DNA i.e. non-genotoxic carcinogens, a tolerable daily intake (TDI) approach is used. A TDI is an estimate of the amount of a substance that can be ingested daily over a lifetime without appreciable health risk and is expressed on a body weight basis. The approach is based on the assumption that there is a threshold dose below which no adverse effects will occur.

The first step involves an evaluation of the available toxicity data which is usually generated from laboratory animal studies, although occasionally human data are available. Ideally a No-Observed Adverse Effect Level (NOAEL), defined as the highest dose or concentration of a chemical that causes no detectable adverse health effects, is identified from these studies. Wherever possible, the NOAEL is based on long-term studies in which the route of administration was via ingestion in drinking-water. If a NOAEL is not available, a Lowest-Observe Adverse Effect Level (LOAEL) may be used, which is the lowest observed dose or concentration of a substance at which there is a detectable adverse health effect. Uncertainty factors are then applied to the NOAEL or LOAEL to derive the TDI. The uncertainty factors which are applied are dependent on expert judgement and can vary but are usually between 10 to 10 000. The sources of uncertainty are listed below:

- Interspecies variation (animals to humans): 1-10
- Intraspecies variation (individual variations): 1-10
- Adequacy of studies or database: 1-10
- Nature and severity of effect: 1-10

TDI = NOAEL or LOAEL (mg $kg^{-1}$ body weight $day^{-1}$)/UF

The guideline value (GV) is then derived from the TDI using the following equation:

$$GV = \frac{TDI \times bw \times P}{C} \ (mg\ l^{-1})$$

where bw = body weight
P = fraction of the TDI allocated to drinking water
C = daily drinking-water consumption

In order to allow for exposure from sources other than drinking water, a percentage of the TDI is allocated to drinking water. Wherever possible, data concerning the proportion of total intake normally in drinking-water (based on means levels in food, air and drinking water) are used in the derivation of the guideline values. However, where such information is not available, an arbitrary (default value) of 10% for drinking water is used.

In the derivation of most guideline values, it is generally assumed that a 60 kg adult consumes two litres of water per day. However, where it is judged that infants or children are at a particularly high risk from exposure to certain chemicals, the guideline

is derived on the basis of a 10 kg child consuming 1 litre of water per day or a 5 kg infant consuming 0.75 litres per day.

Examples of chemicals for which guideline values have been derived using a TDI approach are:

a) xylene which is not carcinogenic and
b) atrazine, a non-genotoxic carcinogen.

a) Xylene

Long-term carcinogenicity studies involving xylene have shown no evidence for carcinogenicity and mutagenicity tests have also proved negative. A TDI of 179 $\mu g\ kg^{-1}$ body weight $day^{-1}$ was derived by applying an uncertainty factor of 1000 to a NOAEL of 250 mg $kg^{-1}$ bw $day^{-1}$ based on decreased body weight in a 103 week gavage study in rats (administration five days per week). Assuming a 60 kg adult drinking 2 litres of water per day and allocating 10% of the TDI to water, a guideline value of 500 $\mu g\ l^{-1}$ (rounded figure) was derived.

b) Atrazine

There is evidence that atrazine can induce mammary tumours in rats, although the weight of evidence from a wide variety of genotoxic assays indicates that atrazine is not genotoxic. No significant neoplasia has been observed in mice. By applying an uncertainty factor of 1000 (100 for inter- and intraspecies variation and 10 to reflect potential carcinogenicity) to a NOAEL of 0.5 mg $kg^{-1}$ bw $day^{-1}$ in a carcinogenicity study in the rat, a TDI of 0.5 $\mu g\ kg^{-1}$ bw $day^{-1}$ was calculated. Allocating 10% of the TDI to drinking water and assuming a 60 kg adult drinking 2 litres of water per day, a guideline value of 2 $\mu g\ l^{-1}$ was derived (rounded figure).

For carcinogenic chemicals which react with the genetic material (DNA) within a cell i.e. are genotoxic, the approach for deriving drinking water guidelines is quite different. This is because this process theoretically does not have a threshold and consequently there is a level of harm at any level of exposure. For such chemicals, the development of a TDI is considered inappropriate and mathematical low-dose risk extrapolation is applied.

Guideline values are determined using mathematical models, and the values presented as the concentration in drinking-water associated with an estimated excess lifetime cancer risk of $10^{-5}$. This risk equates to one additional cancer case per 100 000 of the population ingesting drinking water containing the substance at the guideline value for 70 years. Although several models exist, the linearised multistage model is generally adopted in the development of the guidelines. However, it should be emphasised that the models used are conservative and therefore should be considered at best as a rough estimate of the cancer risk.

Acrylamide is one example of a chemical for which the drinking water guideline was derived using a mathematical model approach. In a long-term carcinogenicity study in rats exposed via drinking water acrylamide induced scrotal, thyroid, and adrenal tumours in males, and mammary, thyroid and uterine tumours in females. The balance

of evidence also indicates that it is genotoxic. On the basis of combined mammary, thyroid and uterine tumours observed in female rats and using the linearised multistage model, a guideline value of 0.5 $\mu g\ l^{-1}$ was derived which was associated with an excess lifetime cancer risk of $10^{-5}$.

For chemicals where the concentration associated with a $10^{-5}$ excess lifetime cancer risk is not practical because of inadequate analytical or treatment technology, a provisional guideline value is set at a practicable level and the estimated associated cancer risk presented.

# APPENDIX B REVIEW OF STANDARD SETTING PROCEDURES FOR LAND

## B1 SUMMARY OF APPROACHES AND IMPLIED RISK

### B1.1 Background

The protection of soil from the potentially detrimental impact of potentially toxic elements (PTEs), and heavy metals in particular, has been a major issue in European countries and North America and the technical literature relating to the possible impact of PTEs in soil is vast. There is also a proliferating number of environmental Standards for PTEs in soil which can be identified in different countries and these have been developed using a variety of different methodological procedures. Some development of Standards for organic pollutants in soil has also taken place, but is more difficult due to the paucity of technical data available on environmental activity and significance of these compounds compared with PTEs. Some researchers have argued that the necessary fundamental information on soil-metal interactions is lacking for ecotoxicological modelling of metal effects, from which appropriate Standards can be derived (McGrath 1993). Despite the possible limitations, however, Standards have been developed which aim to protect the environment from the potentially harmful effects of soil contamination with PTEs.

The sources of environmental Standards addressed in this review provide examples of the technical basis to the development of limit values for PTEs in land application of sewage sludge, and in the derivation of numerical limits for industrially contaminated land. The sources reviewed are not an exhaustive list, but are considered to be representative of the current thinking on the approaches to soil quality protection. The technical bases for soil Standards are reviewed and worked examples of how limits for zinc and cadmium are derived in particular have been presented. These elements have been selected because they are ubiquitous in the environment, are relatively labile in soil and their presence in soil at high concentrations has established environmental consequences.

### B1.2 Summary of approaches

A review of the scientific basis to the Standards for recycling sewage sludge on agricultural land has recently been published (Smith 1996). In addition, the policies for contaminated land and soil quality criteria in some industrialised countries have been reviewed by Visser (1994).

The methodologies adopted in developing soil quality Standards have produced widely differing numerical limit values for PTEs. To illustrate this, the limit values for the heavy metals most frequently of concern in land contamination (zinc, copper, nickel, cadmium, lead, mercury, chromium and arsenic) have been abstracted from the

identified sources and are presented in Table B1. It is evident that the maximum permissible soil concentrations considered appropriate in different countries vary by up to two orders of magnitude.

In general terms two basic approaches have been used to determine the significance of PTEs in sludge-treated agricultural land; a mass-balance approach and an approach based on a technical assessment of toxicity data. Both approaches are equally valid, but they confront the problems and issues of soil contamination from different philosophical perspectives and the numerical Standards so derived are widely different. A policy decision has to be made to determine which path should be followed based on a global perspective and evaluation of economic, environmental, agronomic, practical and social factors. In addition, risk based models are used by some regulatory authorities to derive Standards for both sludge treated land and contaminated land.

### B1.2.1 Mass-balance approach

The objective of this approach is to minimise and, ultimately, to prevent altogether the accumulation of pollutants in agricultural soil and has been adopted for the control of sewage sludge use in agriculture in a number of countries including Denmark, the Netherlands and Sweden (Smith 1996). This approach does not require a technical knowledge of the possible interactions between PTEs in soil and the environment. The ultimate end-point is to maintain the *status-quo* between pollutant inputs to the soil in fertilisers, manures and from atmospheric deposition with pollutant outputs principally in the removed portions of harvested crops thus avoiding any net accumulation within the soil - the so-called 'metal balance approach' (van Driel and Smilde 1990). The numerical limits are therefore necessarily highly stringent. This approach guarantees the multi-functionality of soil by maintaining its original ecological and chemical integrity, but is highly restrictive to recycling opportunities for secondary resources, such as sewage sludge. Remediating contaminated soils to achieve these Standards would appear to be impractical, expensive and technically difficult. Since this is a policy driven approach, and does not require a technical understanding of pollutant behaviour and fate in soil, Standards derived following the mass-balance system have not been considered further here.

### B1.2.2 Technical assessment approach

This approach to Standards development is based on using the available technical information in deriving soil Standards which prevent harmful effects on considered sensitive environmental end-points or pathways. The assumption made, which appears to be supported by available scientific evidence, is that the performance, activity or health of an environmental receptor will remain unchanged as the concentration of a polluting compound in the soil increases until a point is reached where disruption or damage may become apparent. The concentration just below the point where detectable changes occur is called the Highest No Observed Adverse Effect Concentration (HNOEC). The Lowest Observed Adverse Effect Concentration (LOAEC) is an actual measured detrimental effect on a receptor, which may include human or animal health, plant yield or the presence, activity, or diversity of soil organisms. These values are taken directly and used to define protective soil

**Table B1** **Numerical limits for PTEs (mg $kg^{-1}$ dry soil) in sludge treated agricultural soil and in industrially contaminated land from various national and international sources**

| Source | Zn | Cu | Ni | Cd | Pb | Hg | Cr[(1)] | As |
|---|---|---|---|---|---|---|---|---|
| CEC (1986) | 150-300 | 50-140 | 30-75 | 1-3 | 50-300 | 1-1.5 | no limit set | no limit set |
| UK SI (1989)/UK DoE (1989) | 300[(2)] | 135[(2)] | 75[(2)] | 3 | 300 | 1 | 400 | 50 |
| UK DoE (1995) | 200[(3)] | 135[(4)] | 75[(4)] | 3 | 300 | 1 | 400 | 50 |
| NMHSPE (1994) | | | | | | | | |
| (a) 'Standard' soil[(5)] | 140[(6)]-720[(7)] | 36-190 | 35-210 | 0.8-12 | 85-530 | 0.3-10 | 100-380 | 29-55 |
| (b) 'sensitive' soil[(8)] | 426 | 117 | 120 | 7.8 | 386 | 7.8 | 266 | 37 |
| Danish: Scott-Fordsmand and Pedersen (1995) | 100 | 30 | 10 | 0.3 | 50 | 0.1 | 50 | 2 |
| US EPA (1993)[(9)] | 1500 | 775 | 230 | 20-39[(10)] | 190-300[(10)] | 9-17[(10)] | 1540 | 32 |
| WHO: Chang *et al.* (1993) | no limit set | no limit set | 850 | 7 | 150 | 5 | 3200 | 9 |
| ICRCL (1987) | 300 | 130 | 70 | 3-15 | 500-2000 | 1-20 | 600-1000 | 10-40 |

Notes to Table B1:

(1) Total or Cr (III)

(2) Soil pH 6-7

(3) Soil pH 5-7

(4) pH qualification under review

(5) 'Standard' soil (25% clay/10% organic matter)

(6) Target value and (7) Intervention value

(8) Intervention values calculated for 'sensitive' soil (10% clay/2% organic matter) using substance dependent constants (A, B and C) and the equation:

$$I_e = I_{st} \times \frac{A + B \times \%clay + C \times \%org.mat}{A + B \times 25 + C \times 10}$$

(9) Values derived from cumulative application limits for PTEs

(10) Range given where sludge ingestion is critical pathway of exposure: the lower value is the estimated soil concentration based on a cumulative application limit and the upper value is the actual 'clean' sludge limit

framework for recycling sewage sludge on agricultural land, so encouraging the beneficial use of sludge rather than maintaining mass-balances of metals. It also provides the scope for assessing the significance of pollutants in industrially contaminated land in relation to designated future use and the possible extent of remediation required.

### B1.2.3 Approach using risk-based models

Numerical limits may also be calculated on the basis of risk assessment models using available information on dose-response relationships, between metal concentrations in soils and environmental end-points. However, very often the ranges of soil concentration values available in the scientific literature may not adequately cover the upper critical range for certain sensitive pathways and so intuitive extrapolation of responses to a particular toxicant may be necessary. Risk models incorporate a quantitative factor which establishes the level of risk which is considered acceptable. This may be in the form of a probability value (normally for carcinogens), lethal concentration or dose (e.g. $LC_{50}$) or acceptable (or tolerable) daily dietary intake (ADI or TDI) with an implicit margin of safety depending on the properties of the contaminant and the sensitive pathway of concern. Such models have been used to calculate Standards which are considered to protect sensitive receptors exposed via various pathways (US EPA 1993, Ferguson and Denner 1993) or to indicate the quality at which soil is considered to be seriously contaminated (NMHSPE, 1994).

# B2 CASE STUDIES

## B2.1 Case Study 1: EU Directives and associated UK Regulations relating to agricultural use of sewage sludge

The specific technical basis to the EU Directive on sludge use in agriculture (CEC, 1986) is difficult to find in the scientific literature and the ranges of soil limit values set out in this Directive probably reflect a background of local experiences in individual countries and a precautionary approach to soil contamination with PTEs from recycling sewage sludge on agricultural land. However, the extent of the environmental protection offered by the maximum permissible soil concentration in the Directive can be demonstrated by the scientific basis to the UK regulations for sludge (UK SI, 1989; UK DoE, 1989) that implement the requirements of the Directive. The scientific basis to the UK limits ensures that the potentially phytotoxic effects of zinc, copper and nickel on the yield of agricultural crops are avoided. The human food chain is protected from an adverse dietary intake of cadmium by the soil limit for this element. Soil Standards for molybdenum, selenium, lead and fluoride have been derived to protect animal health and the human foodchain.

### B2.1.1 Phytotoxicity

The methodologies used for defining appropriate limit values for the phytotoxic elements involve growing crop species in pot and field trials and statistically comparing

the dry matter yield response at increasing concentrations of metals in soil. In this way the upper critical soil concentration (HNOAEL) is defined. In a pot trial with ryegrass, for example, Davis and Carlton-Smith (1984) reported upper critical soil concentrations for zinc and nickel of 319 and 221 mg $kg^{-1}$, respectively, whereas the regulations stipulate maxima for these elements of 300 and 75 mg $kg^{-1}$, respectively. A specific numerical safety factor is not applied to the data, but is implied because of testing under "worst-case" conditions. For example, soil limits are tested using pot culture techniques, sensitive coarse-textured soils, sludges of controlled, albeit high, metal content and crop species which are particularly sensitive to metal accumulation such as leaf beet. All of these factors increase the extent of metal accumulation in crops and result in lower critical soil concentrations for the phytotoxic elements. Pot trial methodologies have used soils amended with sludges of controlled metal content and soils taken from the field, which have received long-term applications of sludge; so-called "historic site soils". Field trials have demonstrated the safety of the UK statutory limits for potentially phytotoxic metals. However, actual LOAELs have not been measured by realistic field experimentation (Carlton-Smith. 1987). The absence of yield reductions in field trials on historic site soils with soil metal concentrations several times the current limits suggests there is a high although undefined margin of safety against phytotoxicity.

### B2.1.2 pH dependent metal accumulation

The EU Directive also requires that the effects of possible increases in metal uptake as a result of declining pH by crops grown on sludge treated soils, are considered in national Standards. In the UK, the significance of soil pH is examined by field and pot trials using soils from experimental field sites and from historically treated sites. The Standards for phytotoxic elements are defined under reasonably 'worst-case' conditions for soils of pH 6-7 and are regarded as conservative values. Therefore, the proportional changes in crop uptake of PTEs under conditions of lower soil pH compared with a pH of 6-7 are used to calculate appropriate and reduced limits for banded pH ranges of 5.0-5.5 and 5.5-6.0. A margin of safety is implicit within this calculation. No sludge application is allowed below pH 5 due to the large increase in PTE lability which occurs in acid soils.

### B2.1.3 Toxic effects to humans and animals

A different approach to setting the soil Standard for cadmium has been adopted because cadmium accumulation in crops can reach concentrations which may be regarded as potentially toxic to animals and humans before it becomes phytotoxic. Here it has been necessary to construct a dietary model incorporating dose-response relationships between soil and crop cadmium concentrations for the principal and staple crops consumed in the average diet (Carlton-Smith 1987). The dose-responses have been determined by field experimentation on different soils to take account of the differences in PTE lability in soils of contrasting textural properties and pH. Assumptions have been made concerning the amounts of different plant foods consumed by an average individual and the proportion originating from contaminated soil. In the absence of more detailed information it is assumed that all of an individuals plant food comes from soil containing the maximum permissible cadmium

concentration of 3 mg $kg^{-1}$, except for wheat. With wheat, the assumption is that only 2% of intake in bread, etc, will originate from contaminated soil, corresponding with a conservative estimate of the area of agricultural land treated with sludge. The estimated dietary intakes for the different soils are compared with the conservative Acceptable Daily Intake (ADI) of 70 µg Cd $d^{-1}$ for a 70 kg person for cadmium, as defined by WHO Expert Committee on Food Additives. This forms the basis of the risk value in the model. The experimentally derived intakes of cadmium estimated by the model are listed in Table B2.

**Table B2 Estimated dietary intakes of Cd (µg $day^{-1}$) at a soil limit of 3 mg Cd $kg^{-1}$ (Carlton-Smith, 1987)**

| Food groups | Soil type | |
|---|---|---|
| | Sandy loam | Calcareous loam |
| Bread and cereals | 6.66 | 6.19 |
| Cabbage and legumes | 1.01 | 0.92 |
| Leafy salads | 0.68 | 0.27 |
| potatoes | 8.80 | 4.84 |
| Root vegetables | 12.9 | 4.35 |
| Non-impacted foods | 3.7 | 3.7 |
| Total ± 95 % con. Limit | 34 ± 9.5 | 20 ± 5.0 |

The results show a large margin compared with the recommended maximum tolerable intake of cadmium in the diet. However, the assumption that all plant foods originate from sludge-treated soil is regarded as overly conservative in assessing the potential risks of cadmium in sludge-treated soil to the human foodchain and a value of 10% of grown produce is considered as a more appropriate, albeit still precautionary, estimate for the purposes of risk assessment (MAFF/DoE 1993a). Thus, an explicit safety factor is not applied directly in the calculation of the soil Standard, but a margin of safety is implicit within the assumptions made in the dietary model.

### B2.1.4 Effects on microbial processes

In the early 1970s when the development of soil Standards was under consideration for the first time in the UK, the potential for effects on soil microbial processes was examined. This work formed some of the earliest ecotoxicological studies on sludge-amended soils. However, the experimental assays available at that time, which included tests for carbon and nitrogen mineralisation, suggested that these processes were robust and unlikely to be impacted in sludge-treated soils so effort was diverted to protecting crop yields and the food chain which were considered as more sensitive. Recently, however, evidence has been found of potential ecological impacts occurring

at the current UK and maximum permissible EC Standard for zinc (MAFF/DoE, 1993b) based on studies of the numbers and diversity of the symbiotic nitrogen-fixing *Rhizobium leguminosarum* bv. *trifolii* in sludge-treated field experiments. The apparent effects on the numbers of *Rhizobium* in a field trial at Braunschweig in Germany (Figure B1) has formed the basis of a recommendation to reduce the UK soil limit for zinc to 200 mg $kg^{-1}$ for all soil of pH 5-6 (MAFF/DoE, 1993b). The UK Government has undertaken to incorporate this into a revision of the voluntary code of practice for the agriculture use of sewage sludge (UK DoE, 1995b). This is an interesting development and indicates a move away from the classical phytotoxicity approach to a microbially derived Standard using actual LOAELs measured by long-term field experimentation. Whether the field experiment itself represents a realistic model of what actually happens in sludge-treated soils in the practical farming situation is a question for debate. Another point is that *Rhizobium leguminosarum* bv. *trifolii* represents one species of soil bacteria. It is estimated that 20 000 - 40 000 species of bacteria may be present in one gram of soil. The soil microbial community also includes viruses, fungi, yeasts, protozoa and nematodes. Virtually nothing is known about the possible impacts on this vast range of organisms and Standards which protect rhizobia may not protect other potentially more sensitive species and forms. The end-point of this argument is the preservation of the biodiversity of the soil ecosystem, which may become increasingly important as an ecotoxicological indicator of contaminated soil quality.

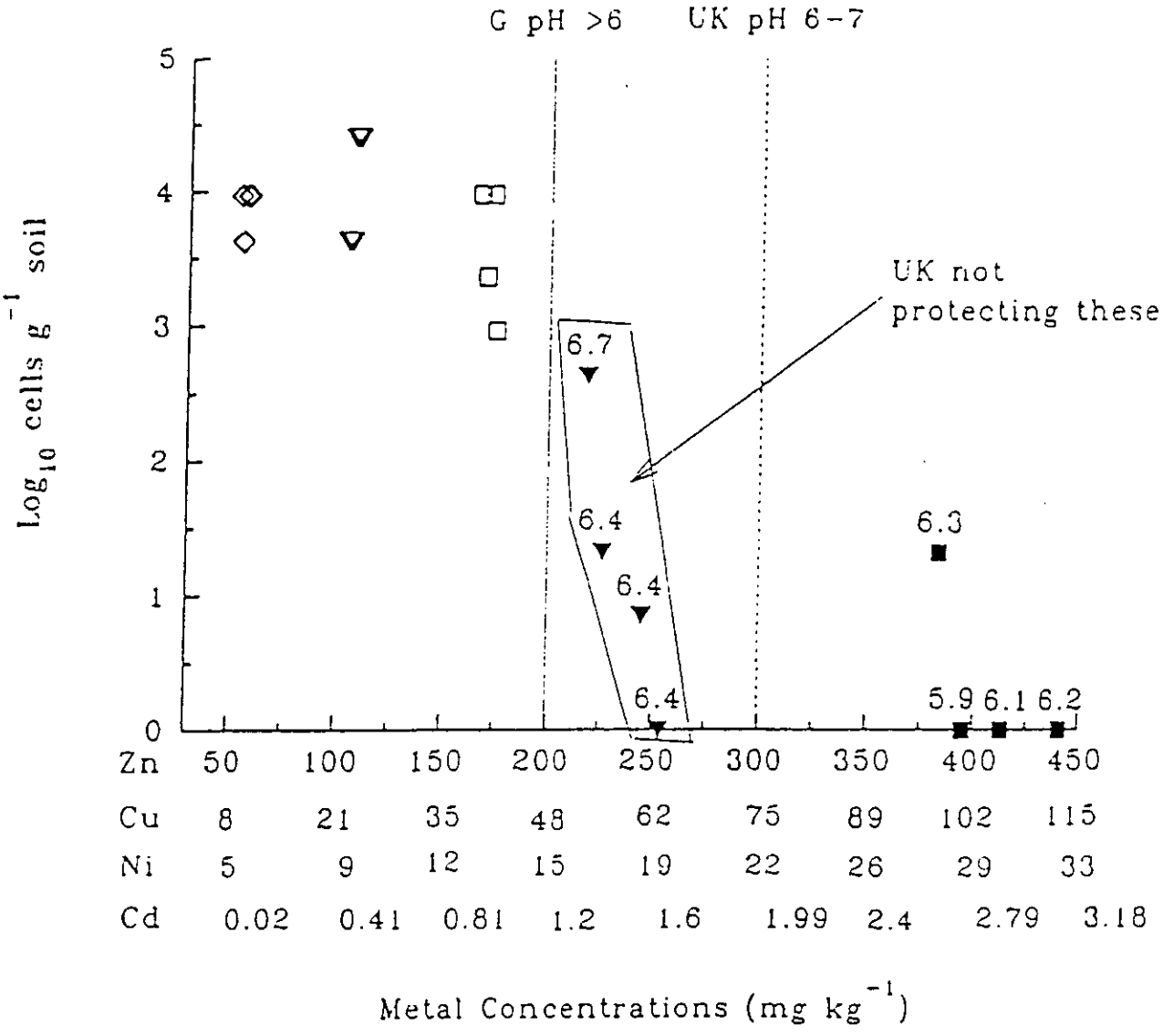


**Figure B1** **Example of the application of actual LOAEL concentrations in setting Standards for PTEs in soil based on the numbers of *Rhizobium leguminosarum* bv. *trifolii* in soil from a sewage sludge-treated field experiment**

# B3 OTHER PROCEDURES

## B3.1 US EPA Final Part 503

The recent US EPA regulations for using or disposing of sewage sludge, published under the Clean Water Act, Section 503, are based on a rigorous risk analysis of 14 sensitive environmental pathways (US EPA, 1992; Table B3) for 10 selected priority PTEs present in sludge (US EPA, 1993). The risk-based models were designed to limit exposure of a highly exposed individual (HEI) to the pollutants of concern. The HEI is defined as an individual who remains for an extended period of time at or adjacent to the site where maximum exposure occurs. Depending on the pathway of exposure, the HEI could be a human, plant, animal or environmental end point, such as surface or groundwater. The concept of a Most Exposed Individual (MEI), considered in the proposed rule, of a hypothetical individual who would be expected to experience the greatest risk and, therefore, required the greatest protection, was dropped from the Final Part 503 as an unrealistic 'worst case' scenario of environmental exposure. The US EPA changed the exposed individual in the risk assessment from the MEI to the HEI to protect individuals and populations that are 'highly exposed to reasonably anticipated adverse conditions'.

Based on the risk assessment, of the application of PTEs to soil in sludge, phytotoxicity (Pathway 8) has been identified as the most limiting for zinc, copper and nickel, whereas for cadmium, lead and mercury, sludge ingestion by young children has been identified as the most limiting pathway. In contrast to the UK approach, the US EPA risk assessment compiles all available experimental data from field trials to calculate appropriate dose-response relationships for the phytotoxic elements. The relationships between soil and crop metals obtained from pot trials and from studies with metal salts are deliberately excluded from the data set as they exaggerate the toxic effects of metals compared with sludge and are considered as unrealistic of actual toxicity responses observed in the field. Two basic approaches are then applied based on the (i) probability of a metal input causing a yield reduction or on (ii) achieving a threshold phytotoxic concentration in plant leaves. In Approach (i), the entire data set is used to determine the highest loading rate having less than a 1% probability of exceeding an acceptable tolerance threshold which is set at 50% growth reduction. Since this analysis may not protect the most sensitive crops to phytotoxicity, approach (ii) uses LOAEL values for the concentrations of elements in plant leaves associated with the first detectable reduction in growth. The geometric mean uptake slope for leafy vegetables (which are the most sensitive crops to phytotoxicity) is used to back calculate the appropriate loading rate corresponding with the selected LOAEL value. For zinc, a LOAEL for lettuce of 400 mg $kg^{-1}$ in plant leaves is used in the calculations. This value is at the upper range of leaf zinc concentrations considered to be tolerable in agricultural crops (Kabata-Pendias and Pendias, 1992) and may have little additional intrinsic safety.

**Table B3 Environmental pathways of concern identified for application of sewage sludge to agricultural land (US EPA 1992)**

| Pathway | Description of 'Highly Exposed Individual' (HEI) |
|---|---|
| 1. Sewage sludge→Soil→Plant→Human | Human ingesting plants grown in sewage sludge-amended soil |
| 2. Sewage sludge→Soil→Plant→Human | Residential home gardener |
| 3. Sewage sludge→Human | Children ingesting sewage sludge |
| 4. Sewage sludge→Soil→Plant→ Animal→ Human | Farm households producing a major portion of the animal products they consume. It is assumed that the animals eat plants grown in soil amended with sewage sludge |
| 5. Sewage sludge→Soil→Animal→ Human | Farm households consuming livestock that ingest sewage sludge while grazing |
| 6. Sewage sludge→Soil→Plant→Animal | Livestock ingesting crops grown on sewage sludge-amended soil |
| 7. Sewage sludge→Soil→Animal | Grazing livestock ingesting sewage sludge |
| 8. Sewage sludge→Soil→Plant | Plants grown in sewage sludge-amended soil |
| 9. Sewage sludge→Soil→Soil organism | Soil organisms living in sewage sludge-amended soil |
| 10. Sewage sludge→Soil→Soil organism→ Soil organism predator | Animals eating soil organisms living in sewage sludge-amended soil |
| 11. Sewage sludge→Soil→Airborne dust→ Human | Tractor operator exposed to dust while ploughing large areas of sewage sludge-amended soil |
| 12. Sewage sludge→Soil→Surface water→ Human | Water Quality Criteria for the receiving water for a person who consumes 0.04 kg $day^{-1}$ of fish and 2 l $day^{-1}$ of water |
| 13. Sewage sludge→Soil→Air→Human | Human breathing volatile pollutants from sewage sludge |
| 14. Sewage sludge→Soil→Groundwater→ Human | Human drinking water from wells contaminated with pollutants leaching from sewage sludge-amended soil to groundwater |

In contrast to the potential dietary exposure experienced due to crop uptake of cadmium, which is usually considered as the principal concern in sludge-treated soil, the risk assessment methodology identifies the direct ingestion of sludge and sludge-treated soil by children (Pathway 3) as potentially more limiting. Transfer to the human diet *via* plant produce grown on sludge amended soil is considered in the analysis of risk under two contrasting scenarios of exposure. For agricultural utilisation (Pathway 1) the HEI is an individual consuming 2.5% of their food plant from sludge-amended farmland and the duration of exposure is for a lifetime of 70 years. To quantify dietary exposures resulting from land application of sewage sludge, the amounts of various food types consumed over a lifetime are determined for the population as a whole. This involves estimating the quantities of unprocessed commodities consumed in complex prepared foods and calculating the average intake over a lifetime for each food category by weighting according to sex and age group. Relationships between plant tissue concentrations and cumulative pollutant loading rates are obtained from the scientific literature and geometric uptake slopes calculated for each of the major food plant groups. These include grains and cereals, potatoes, leafy vegetables, legumes, root vegetables and garden fruits. Finally, the Agency uses the WHO recommended maximum daily intake for cadmium of 70 $\mu g\ day^{-1}$ to calculate the allowable intake over and above the background level which is estimated to be 16.14 $\mu g$ Cd $day^{-1}$. It is emphasised that the recommended maximum tolerable intake of Cd appears to be without appreciable risk to human health during an entire lifetime on the basis of current knowledge. Therefore, US EPA calculate that an additional 53.86 $\mu g$ Cd $day^{-1}$ could be ingested above the background level with minimal adverse effects. Within this risk framework an estimated 610 kg $ha^{-1}$ of cadmium could be applied to agricultural land without affecting human health adversely. This value corresponds to a soil concentration of 305 mg Cd $kg^{-1}$.

A group of individuals receiving potentially higher level of cadmium exposure in consumed plant foods are home gardeners. This is because a larger proportion of the plant component of the diet might by grown on significantly contaminated soil. The HEI in this pathway of exposure (Pathway 2) is an individual consuming 59% of their fruit and vegetable intake and 37% of the intake of potatoes, for 50 years, grown on a garden containing the maximum allowable cumulative cadmium application. As expected, due to the increased likelihood of exposure to cadmium, the estimated safe loading rate to protect the home gardener is lower than the purely agricultural route and is 120 kg Cd $ha^{-1}$, which corresponds to a soil limit value of 60 mg Cd $kg^{-1}$ without the risk of adverse effects.

The Standard for cadmium in the Final Part 503 rule is set by Pathway 3 to protect young children from directly ingesting sewage sludge. In this scenario, the HEI is a normal child between the ages of 1 and 6 who ingests 200 mg $day^{-1}$ (dry solids) of sewage sludge from storage piles or from the soil surface for a maximum period of five years. The risk assessment stipulates that the HEI is not a pica child (i.e. one with abnormal eating habits), because it is assumed that the parents of pica children will take precautions to prevent their children from eating sludge. A pica child would be regarded as an MEI and is therefore considered as an unreasonable and unrealistic level of exposure for the purposes of risk assessment.

With the increasing interest in ecotoxicological impacts of PTEs in soils, the US EPA have also evaluated toxicity to soil organisms in Pathway 9 of the risk assessment. The procedure evaluates the available data on potential toxicity to the earthworm *Eisenia foetida*, as the HEI. Earthworms are not considered as the most sensitive species to PTEs in sludge-treated soil, but are selected because the EPA considers that there are a lack of data available for other organisms. Only copper is evaluated by this pathway, the other PTEs are screened out during an initial evaluation of the possible risks to soil organisms. The NOAEL for copper, which is considered to protect earthworms from adverse effects, is based on a literature value and taken as 1500 mg Cu $kg^{-1}$ (dry soil).

## B3.2 Dutch target and intervention values

Recent changes in Dutch policy on soil remediation has led to the adoption of two sets of soil concentration values for pollutants (NMHSPE 1994, Table B1). *Target values*, which are set to indicate the quality of soil levels ultimately aimed for and reflect the concentrations of PTEs which are normally expected to be found in relatively uncontaminated soils and *Intervention values*, which are set for soil remediation and indicate the quality at which soil is considered to be seriously contaminated. It is stressed that the Dutch soil Standards for contaminated land have been developed for entirely different purposes than the regulations for sludge described earlier. They are not intended for sludge-treated soils. Indeed the Dutch Government is following the 'mass-balance' approach for PTEs (see Section B1.2.1) for the control of sewage sludge applied to land.

The intervention values have been based on a detailed study into human toxicological and ecotoxicological effects of soil contaminants based on a risk assessment approach and the estimation of the Maximum Tolerable Risk (MTR). The human toxicological effects are quantified in terms of those concentrations in the soil which result in the so-called MTR level to humans being exceeded. For non-carcinogenic substances like PTEs, this corresponds to the ADI (also defined as the tolerable daily intake - TDI). The MTR for man is calculated by a mathematical human exposure model called CSOIL. It describes the routes from source (soil) to humans via various pathways, by estimating concentrations in contact media using commonly accepted physico-chemical models. Total estimated exposure for children and adults is compared with the ADI. It is assumed in this part of the analysis that all exposure pathways apply or, in other words, the sum of all the exposures including ingestion in food, inhalation and groundwater are compared with the ADI. Thus the intervention values for groundwater are not based on a separate risk assessment, but are derived from the values calculated for soil/sediment.

Ecotoxicological effects are quantified in terms of concentrations in soils at which 50% of species actually (or potentially) occurring may incur adverse effects. The ecotoxicological risk value, or MTR, known as the hazardous concentration ($HC_{50}$), is defined as the median value of published no effect concentrations (NOAEC), lethal concentrations ($LC_{50}$) and effect concentrations ($EC_{50}$). At the time of writing it is not clear which organisms, soil processes or experimental procedures are used in estimating the $HC_{50}$. However, Theelen *et al* (1995) have reported that the NOAECs

for soil process organisms are less sensitive than those for effects on populations and diversity.

Intervention values are finally derived by integrating the human and ecotoxicological risk values. In all cases intervention values for the principal elements (zinc, copper, nickel, lead, chromium and mercury) are based on ecotoxicological effects which are found to be more sensitive to soil contamination than human toxicology.

In contrast to the UK Standards for sludge-treated soil which are graded according to soil pH, the Dutch system does not consider soil pH directly but makes adjustments to the target and intervention values according to differences in soil texture (clay content) and organic matter status.

## B3.3 Danish soil quality criteria

The Danish Government has published a list of ecotoxicologically derived soil quality criteria (SQC) for a range of selected substances including inorganic compounds (Scott-Fordmand and Pedersen, 1995). These criteria are set at a level where no harmful effects on soil organisms or processes are expected. The approach uses NOAEC or LOAEC values for soil dwelling organisms, including invertebrates, plants, micro-organisms and microbial processes. The objectives of the ecotoxicologically derived SQC are to protect the function and structure of soil ecosystems. Since not all organisms and functions in an ecosystem can be tested against all possible chemicals and combinations of chemicals, extrapolation from simple laboratory tests to the ecosystem level has been attempted. However, the extrapolation procedures adopted which include either (i) the application of a safety factor of between 10 and 1000, depending on the quality of the test data (see Table B4), or (ii) derivation of a protection level for 95 % of organisms with a statistical confidence of 95 %, cannot be applied to metals. The aim of the safety factors, for example, is to account for interactive effects of chemicals, intra-/interspecies variation, differences between chronic and acute effects, and differences in effect concentrations between field and laboratory studies. However, the extrapolation procedures failed because it could not be assumed that the derived NOAECs reflected differences in species sensitivity to PTEs. This is partly due to the common practice of exposing test organisms to soluble metal salts in experiments resulting in NOAEC values that do not reflect NOAECs obtained in the field (i.e. toxicity under field conditions is generally lower due to reduced bioavailability). Moreover, some organisms have the ability to regulate metal uptake and excretion and can also adapt to increased soil concentrations. Consequently, in recommending an appropriate SQC, direct evaluation of field data is necessary in order to identify NOAECs for the ecosystem that take into account the fate and bioavailability of the chemical in question.

In essence, the Danish SQC values have been derived from a review of world-wide literature of studies involving the application of metal salts (principally chloride, sulphate and nitrate) to soil. Applied metal salts are generally much more toxic to biological systems in soil than contamination arising due to industrial activity (e.g. atmospheric deposition) or agricultural activities (e.g. sewage sludge application). Compared with other soil Standards listed in Table B1, the SQC values are very

stringent. This is emphasised since they are also lower, and sometimes significantly lower, than the Dutch target values set for uncontaminated soil.

**Table B4 Safety factors used in the determination of Dutch soil quality criteria (SQC) (Scott-Fordsmand and Pedersen, 1995)**

| Information available | Safety factor[1] |
|---|---|
| The lower end of the acute $LC_{50}$ range, where available data are few or the range of organisms narrow, considering that outlier values may be due to chance error or experimental conditions that deviate excessively from field conditions.[2] | 1000 |
| The lower end of the range of acute $L(E)C_{50}s$ when there is an extensive database covering a wide range of different test species, *or* to the lower end of the chronic $L(E)C_{50}s$, *or* NOAEC values when few data are available. | 100 |
| The apparent NOAEL where this is based on sufficient and representative data. | 10 |

Notes to Table B4:

(1) The LOAEC or NOAEC is divided by this factor

(2) Authors note: It would appear that this approach would exacerbate the error of test procedures which do not reflect field conditions, notably those using applied metal salts, which already overestimate potential toxicity and underestimate the LOAEL. Most test procedures are designed to be 'sensitive' so further division would lower the LOAEL to an unrealistic value compared with the effects which might be expected under field conditions.

Furthermore, the SQC of some of the elements actually fall within the normal range of background soil concentrations found in Denmark. This seems to be particularly relevant for cadmium where the SQC is given as 0.3 mg Cd $kg^{-1}$ yet an upper range for background soil concentrations in Denmark is 0.6 mg Cd $kg^{-1}$. For comparison, the UK median and upper range background soil concentrations are presented in Table B5, with reported average values alongside ranges for Danish soils. Background concentrations of PTEs in UK soils are typically higher than those measured for Danish soils. For example, the UK median soil cadmium content is 0.7 mg $kg^{-1}$. At face value the SQC would suggest that adverse effects on soil ecology could be anticipated at the background concentrations of PTEs normally found in the UK. This has not been observed in practice.

The objective of the SQC is to guarantee the ecological integrity of the soil environment and so it is accepted that they will be necessarily highly precautionary. The SQCs were derived from a world-wide survey of scientific literature and so, by

definition, they should be widely applicable. However, an initial comparison of SQC values with background soil concentrations suggests that this does not appear to be the case. Simply identifying and adopting the lowest LOAEC or NOAEC in the literature as the SQC, based on laboratory studies with metal salts, may not necessarily be applicable to soil protection in the field. Therefore, these observations must call into question the relevance of the SQC values in relation to soil protection policy and they suggest that a more careful and pragmatic assessment and interpretation of the scientific literature might be necessary. It also emphasises the difficulties in developing Standards for soil that will gain the confidence of the regulatory authorities and the public at large by demonstrably protecting the soil whilst, at the same time, being both pragmatic and realistic.

**Table B5 Typical total concentrations of PTEs (mg $kg^{-1}$ dry soil) in Danish and UK soils**

| PTE | Denmark | United Kingdom[1] | |
|---|---|---|---|
| | Mean or range | Median | Upper range[2] |
| Zn | 10-80 | 82 | 181 |
| Cu | 6-20 | 18.1 | 43.3 |
| Ni | 6.0 | 22.6 | 60.0 |
| Cd | 0.22 | 0.7 | 1.7 |
| Pb | <20 | 40 | 123 |
| Cr | 11-21 | 39.3 | 91.5 |

Notes to Table B5

(1) McGrath and Loveland, 1992

(2) Corresponds with the upper hinge of the percentile range in soil

## B3.4 German action values for $NH_4NO_3$ extractable PTEs

Background, action and threshold values for $NH_4NO_3$-extractable PTEs have been integrated into the regulation for soil protection in the Baden-Württemberg region in Germany (PrÜeβ, 1995) based on the procedure behind the German national Standard (DIN 19730) to determine mobile trace elements in soil by $NH_4NO_3$ extraction. This is an interesting development in that it recognises that it is the mobile forms of PTEs in soils which potentially can have an adverse environmental effect.

Background values are taken as the 90 percentile concentrations for uncontaminated soils and they are adjusted to take account of the increased mobility of most PTEs with decreasing soil pH. These values are used as guidelines in conjunction with background concentrations to estimate the total element concentrations in soil.

Action values are estimated from the relationships with plant yield for phytotoxic elements (e.g. zinc) or concentrations in edible portions of crops for zootoxic elements (e.g. cadmium in wheat grain). Action values are set on the basis that the critical concentrations in plant tissues (i.e. German food and fodder threshold values or upper critical values for plant growth) are not exceeded in 95% of cases. Action values for the activity of soil micro-organisms are obtained from the scientific literature. Microbial Standards are estimated for silver, chromium, copper, mercury and vanadium. Interestingly, zinc is not included in the list of microbial limits. However, the possible effects of Zn on certain soil micro-organisms has been considered a principal concern in sludge-treated soil in the UK (MAFF/DoE 1993b). This emphasises the possible inconsistency in approaches to Standards development in different countries as well as the paucity of data available from comprehensive and reliable field experiments and monitoring studies which can be used for setting universally applicable and appropriate limit values.

Threshold values are more stringent than action values and are set on the basis that the critical concentration values should not be exceeded in more than 70% of cases examined. If a soil exceeds a threshold value, agricultural use of that soil should be limited.

## B3.5 Guidelines for sewage sludge recycling under consideration by WHO

These preliminary numerical limits are designed to provide guidance for the global application of wastewater and sewage sludge and are based on exposure pathways, as adopted by the US EPA (Chang *et al* 1993). The approach is used because of the deficiency of technical data and because the US EPA methodology is considered logically sound. However, rather than taking all exposure routes, only the food chain transfer of pollutants by the waste-soil-plant-human route is considered due to the dietary intake of the pollutant from food consumption of grain, vegetables, roots/tubers and fruit. This restriction is applied because, according to the technical literature, food chain transfer is the primary route of human exposure to environmental pollutants. Based on a global diet, daily intake of these commodities accounts for about 75% of daily food consumption. The global diet itself is assumed to consist of 0.405, 0.212, 0.288 and 0.235 kg fresh weight for grain/cereal, vegetable, root/tuber and fruit, respectively. An exposure scenario is followed that identifies residents living inside a land application area whose plant food intake is exclusively from the sludge-treated area. In light of the earlier discussion on the proportion of food which is actually taken from sludge-affected land, this scenario is regarded as highly conservative within the analysis of exposure risk. This group is assumed to be the most exposed population and, for calculating risk-based soil limit values (see Table B1), it is also assumed that this groups daily intake of pollutants from the consumption of different types of plant food should be limited to 50 % of the ADI.

## B3.6 ICRCL guideline (trigger) values

Current UK guidelines on soil quality criteria for contaminated land are given by the Interdepartmental Committee on the Redevelopment of Contaminated Land (e.g. ICRCL, 1987). However, the validity of this procedure as a basis for assessing the importance and significance of certain contaminants in soil has been questioned (Beckett 1993).Guidance on assessment and remediation of polluted sites is based on 'trigger concentrations' for certain contaminants and intended 'end uses'. In each case, there are two trigger values: a threshold value and an action value. These are used as follows:

- Where all concentrations are below the threshold values, no remedial action is needed for the proposed land use. The risk is no greater than normally expected and the site may be regarded as uncontaminated.

- Where some or all concentrations lie between the threshold and action values, there is a need to consider whether remedial action is required for the proposed use or whether there should be a change in the planned use. The significance of the risk depends on the intended use.

- Where some or all concentrations equal or exceed the action value the risk is considered as unacceptable and the land should be regarded as contaminated. Under these circumstances, some form of remedial strategy is unavoidable.

Action values are listed for certain organic and inorganic chemicals, but have not been published for PTEs. In addition, it is not clear what the scientific basis to the trigger values for PTEs is (Beckett 1993), although the limits apparently consider:

- Uptake of contaminants by food plants grown in contaminated soil (cadmium and lead)

- Ingestion and inhalation of contaminated soil/dust adhering to plant produce or through direct ingestion of soil either deliberately or accidentally by children

- Skin contact e.g. tars, oils, corrosive substances.

- Phytotoxicity (zinc, copper, nickel, boron)

- Water resource contamination

- Fire and explosion risk

- Chemical attack on building materials and services

As far as the threshold values are concerned for protecting human health and plant growth, it seems probable that for some of the PTEs (e.g. zinc, copper, nickel, cadmium, mercury and selenium), the adopted Standards for the domestic gardens/allotments exposure scenario follow the UK regulations on the agricultural use of sludge (UK SI 1989 UK SI DoE 1989).

## B3.7 Development of the DoE tool, CLEA, for assessing risks of contaminated land to human health

The UK DoE is currently sponsoring an ongoing programme of research aimed at improving and extending the advice and guidance available on risk assessment and management of contaminated land. A particularly important area of the research, which is near to completion, but has not formally reported, is a project on the development of generic guideline values for contaminants that are based on assessment of exposure parameters. The Contaminated Land Branch of the DoE was contacted concerning the study, but at this stage, the detailed information remains confidential and will be available later in 1996. For this purpose the Contaminated Land Exposure Assessment (CLEA) model has been developed, which predicts actual exposures of target populations, based on simulation of various exposure pathways for particular land use categories, e.g. residential, recreational or commercial/industrial (Ferguson and Denner 1993). Soil type and other relevant parameters (e.g. pH) can also be specified. In 'reverse mode' the model can predict an appropriate soil concentration value corresponding with a risk or exposure value as the input.

Elements of the model include:

- Calculation of background exposures from fixed background concentrations or from water concentrations according to public water supply;

- Estimation of average daily exposure or risks via various exposure pathways. These include ingestion of soil and dust, consumption of home grown vegetables, skin contact and inhalation of soil, dust and water, as shown in Table B6, for different land uses;

- A computer simulation procedure ('Monte Carlo' model) which produces frequency distributions of exposure or risk, based on an assessment of the expected distributions of variable values of environmental media, physico-chemical properties or exposure parameters. This allows the effects of the intrinsic errors of the parameters within the CLEA model to be tested, in a form of sensitivity analysis using randomly generated values within the limits of normally expected or prescribed error, for each of the input variables in the model. The frequency distribution of the range of possible and tentative output values is generated so that the level of confidence or certainty within the trigger values can be assessed. The Monte Carlo model can be used to test the sensitivity of output to the various input values and model assumptions.

The schematic structure of the CLEA model is shown in Figure B2. The CLEA model provides the mechanics for calculating an appropriate soil Standard for pollutants according to different routes and levels of exposure to protect human health. Implicit within this calculation will be the requirement for an ADI value and some assumptions concerning, for example, the amounts of garden produce consumed that is grown on contaminated soil and the quantities of soil ingested or inhaled. There is no published information currently available indicating what these assumptions might be. However, the risk scenarios which have been outlined appear to deal specifically with conventional human toxicology and do not to take account of ecotoxicological impacts

including possible phytotoxic effects on plants or toxicity to soil organisms, which are considered to be important and potentially more sensitive to soil contamination than impacts on human health.

**Table B6 Exposure routes modelled in the CLEA model, depending on the proposed site after use**

| Exposure route | Resid'l with garden | Resid'l without garden | Rec'n - allotm'ts | Rec'n - parks, open spaces | Comm/ Ind - indoor |
|---|---|---|---|---|---|
| Ingestion of soil (outdoors) | ● | ● | ● | ● | - |
| Ingestion of dust (indoors) | ● | ● | ● | ● | ● |
| Consumption home-grown veg | ● | - | ● | - | - |
| Ingestion of soil/dust on veg | ● | - | ● | - | - |
| Skin-contact, soil (outdoors) | ● | ● | ● | ● | - |
| Skin contact, dust (indoors) | ● | ● | ● | ● | ● |
| Inhalation of dust (outdoors) | ● | ● | ● | ● | ● |
| Inhalation of dust (indoors) | ● | ● | ● | ● | ● |
| Inhalation of vapour (outdoors) | ○ | ○ | ○ | ○ | ○ |
| Inhalation of vapour (indoors) | ○ | ○ | - | - | ○ |

## B3.8 Possible extrapolation from water Standards

It has been suggested that effects data reported in water may be used to extrapolate to values that can be used in risk assessment of soil on the basis of adsorption properties ($K_d$) and water content (w) of the soil in question (Scott-Fordsmand and Pedersen 1995) This can be achieved by the following equation:

$$EC_{soil} = EC_{water} \times (K_d + w)$$

The partition coefficient, $K_d$, of hydrophobic compounds differs from soil to soil, but can be estimated from the octanol-water partition coefficient ($P_{ow}$) of the chemical and the organic carbon content ($f_{oc}$) of the soil as follows:

$$K_d = P_{ow} \times f_{oc}$$

To estimate the partition coefficient of dissociable chemicals, the fraction of the non-dissociated substance must be known. This fraction depends on the dissociation constant ($pK_a$) of the molecule and the pH of the soil as follows:

$$K_{d(adjusted)} = K_d \times (1 + 10^{(pH - pKa)})^{-1}$$

These extrapolations are based on the presumption that primarily the water soluble fraction of the chemical is bioavailable. This is generally regarded to be the case for metal cations and there is also evidence to support this for organic substances.

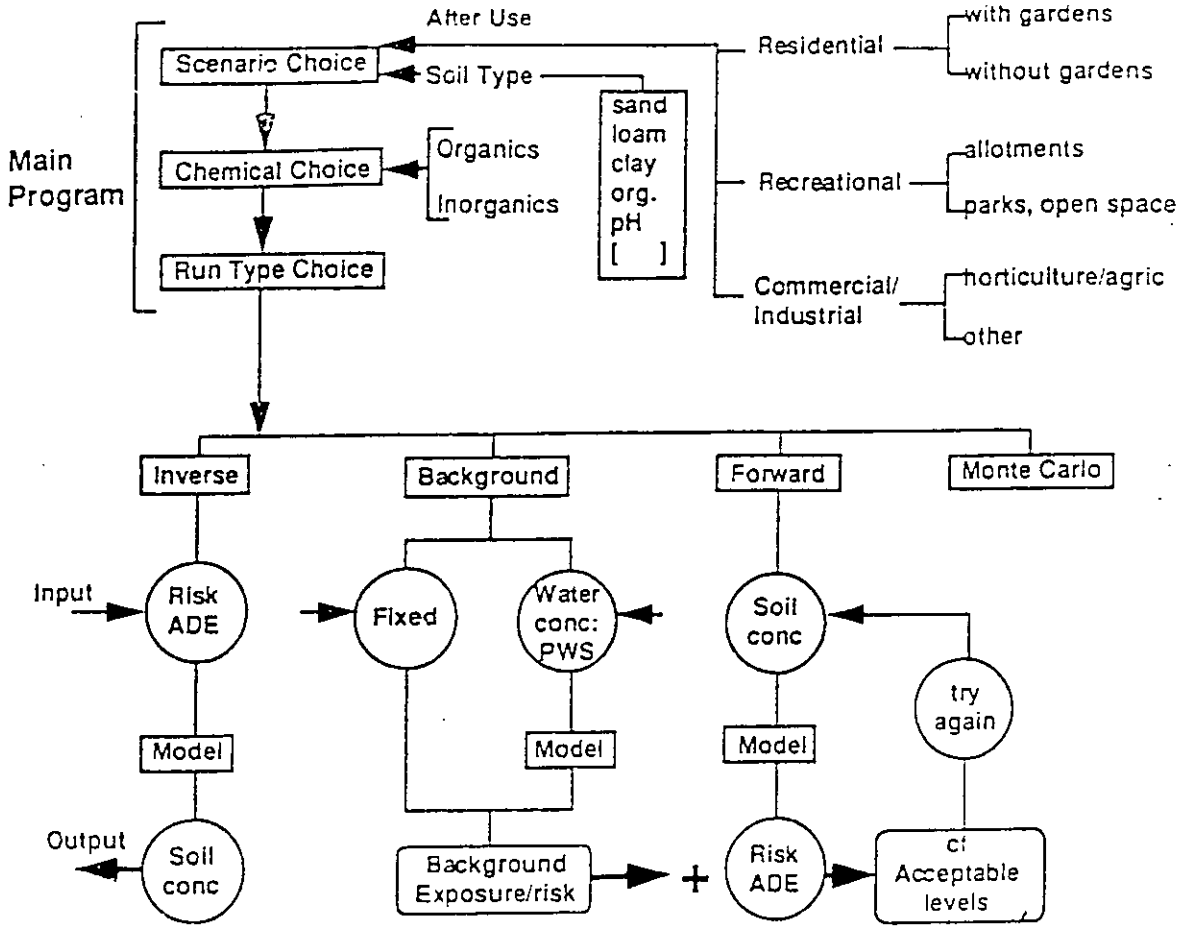


**Figure B2 Schematic representation of the CLEA computer model. ADE = Average Daily Exposure; PWS = Public Water Supply**

# APPENDIX C REVIEW OF STANDARD SETTING PROCEDURES FOR AIR

## C1 SUMMARY OF APPROACHES AND IMPLIED RISK

### C1.1 Background

Concern regarding the effects of atmospheric pollution, particularly smoke, on human health pre-dates the Industrial Revolution of the 18th and 19th centuries. The development of legislation in the UK to control air pollution has been gradual since the 1863 Alkali Works Act (NCSA, 1994). The 1874 version of this Act introduced the concept of best practical means and this Act was subsequently applied to all major industries which polluted the atmosphere. This appendix reviews the procedures underlying national and international air Standards which are currently adopted in the UK.

The majority of air Standards have been derived to protect human health, and therefore have not examined ecological endpoints. The EU Air Quality Directives consider both human health and environmental effects (including effects on buildings) in a single Standard, whereas the WHO Vegetation Damage Thresholds specifically aim to protect ecosystems. Although not enshrined in legislation, the Critical Loads/Critical Levels concept, included in the UN Economic Convention on Long Range Transboundary Air Pollution, is also aimed at the protection of ecosystems through exposure via atmospheric deposition. This procedure also provides for a more integrated approach to pollution control. The majority of ecotoxicological studies that examine the direct effects of atmospheric pollution, are on plants. Therefore, atmospheric Standards that aim to protect ecosystems are primarily based on endpoints of phytotoxicity.

### C1.2 Summary of approaches

For the protection of human health, the same basic derivation procedure is used by the different organisations to derive air Standards. In this procedure, hazards are identified and the toxic nature of the chemical is determined to be either threshold (i.e. acute effects) or non-threshold (i.e. carcinogenic effects). Where appropriate, a threshold is derived below which exposure is not expected to result in any adverse effects on health. Threshold Standards are usually derived by the application of some arbitrary safety factor to either human exposure or laboratory toxicity data. The safety factors used are not always clear and vary from chemical to chemical. Moreover, all procedures appear to rely heavily on expert judgement as a means of assessing hazards and risks on a case by case basis. For chemicals which do not have a safe threshold, the Standard is given as an expression of risk to the human population. In addition, a threshold may also be derived below which the increased incidence of effects is expected to be too low to be measured accurately.

The majority of air Standards have been derived to protect human health, are hazard based and do not have an inherent "acceptable level of risk" either to human populations or the environment. In other words, an assessment of risk is not implicit in the derivation procedures. The exceptions to this are the WHO Air quality Guidelines and IRIS Standards which are derived using mathematical models for carcinogenic substances. These Standards are expressed in terms of risk to human populations. However, some of the other procedures include a qualitative assessment of risk in the expression of their Standards. For example, the air Standards set by EPAQS and the HSE Occupational Exposure Limits, recognise the increased risk of harm to certain sensitive sub-groups of the population (e.g. asthmatics) following exposure to atmospheric pollutants, and set their Standards accordingly.

# C2 CASE STUDIES

## C2.1 Case Study 1: Expert panel on air quality Standards (EPAQS)

### C2.1.1 Background

The Expert Panel on Air Quality Standards (EPAQS) was set up in 1991 by the Secretary of State for the Environment in response to the Environment White Paper "This Common Inheritance" which was published in September 1990. The aim of the panel is to advise as required, on the establishment and application of air quality Standards in the United Kingdom. The Panel develops policies for the control of air pollution and it has a role in increasing public knowledge and understanding of air quality. The Panel assesses the available evidence of the effects of air pollution on human health develops an air quality monitoring network.

### C2.1.2 Procedure

The Panel considers each chemical separately, and to date has derived Standards for benzene, ozone, 1,3-butadiene, carbon monoxide, sulphur dioxide and particles (UK DoE 1994a, 1994b, 1994c, 1994d, 1995c, 1995d). The hazard of the chemical is identified from data on humans, and the applicability of a Standard is justified. An appropriate exposure time must also be derived from the toxicity data. A safety factor may then be applied to the concentration identified as safe in the hazard assessment. The safety factor used varies for each chemical and is applied to determine the risk of the chemical to the general population, rather than to indicate the confidence in the data (as is the case in some other Standard derivation procedures). The Panel may identify possible sub-groups within the population such as asthmatics who may be more susceptible than the general population. Thus a risk-based approach is taken to protect the whole population.

The Standards also take into account other factors such as the ability to measure atmospheric concentrations accurately, and where monitors should be situated to provide the most relevant information. The Standards set by EPAQS apply only to

direct protection of the health of the general population. Effects on the environment such as vegetation, freshwaters and buildings are not considered, although it is hoped that the Standards set contribute to the reduction of these effects.

### C2.1.3 Worked examples

**Sulphur dioxide**

Sulphur dioxide is a respiratory irritant. Acute exposure to high concentrations can lead to irritation of the eyes, nose, mouth and throat. The Panel reported that although data are available to suggest long term effects on human health, such data is too weak and insufficient to be used in the process of Standard setting. The most likely exposure to high sulphur dioxide concentrations is from occupational rather than from ambient air. The Panel noted, however, that of the general population, asthmatics form a sub-group which are most likely to be affected by exposure to sulphur dioxide. The available data for sulphur dioxide suggest that an exposure threshold exists such that toxic effects will only occur following exposures to concentrations above the threshold. The Panel concluded that the majority of asthmatics are unlikely to develop clinical effects following exposure to 200 ppb in ambient air (although most studies did not report any effects in asthmatics exposed to 250 ppb). The Panel also concluded that the sulphur dioxide Standard should be based upon a 15 minute exposure time. This exposure time is the minimum time in which the sulphur dioxide concentration can be accurately measured and controlled. However it is still long enough to allow for high sulphur dioxide peaks which give an average concentration within the safe limit during the 15 minutes. The Panel therefore concluded that the Air Quality Standard for sulphur dioxide should be 100 ppb, measured over a 15 minute exposure time.

The derivation of a Standard for sulphur dioxide took the approach that there should be no risk to any individuals exposed to sulphur dioxide in ambient air. The Standard was derived to protect the most sensitive individuals within a sensitive sub-group of the general population (i.e. asthmatics).

**Benzene**

Acute exposures to benzene can result in narcotic effects in humans leading to death at high concentrations. Benzene is also rated as a carcinogen, and chronic exposures have been associated with development of non-lymphocytic leukaemias. The Panel concluded that due to its carcinogenic nature, there is no benzene concentration which can be deemed to be safe. However, the Panel decided that a concentration at which the risks are unlikely to be detectable by any practicable method may be proposed. The Panel concluded that the increased risk of carcinogenicity in workers exposed to 500 ppb was undetectable. A total safety factor of 100 (two safety factors of 10) was applied to account for continuous ambient exposure and the exposure of more sensitive sub-groups such as children and the elderly. This gives an Air Quality Standard of 5 ppb which the Panel recommended for a year's running average. The Panel additionally advised that in future, this Standard should be reduced to 1 ppb with an annual running average, and that the Government set a target date by which the new Standard should be reached.

As with the sulphur dioxide Standard, the Standard for benzene assumes that there is no risk to human health. The use of the safety factors is somewhat arbitrary. Ambient exposure is on average 10 times greater than occupational exposure, but this assumes that the relationship between exposure time and risk is linear. Application of a second safety factor of 10 is totally arbitrary, although this is somewhat over-ruled by the recommendation that the Standard be reduced to 1 ppb.

## C2.2 Case Study 2: Health and Safety Executive (HSE) Occupational Exposure Limits (OELs)

### C2.2.1 Background

Two types of Occupational Exposure Limit exist: The Maximum Exposure Limit (MEL) and the Occupational Exposure Standard (OES). Exposure to the MEL can imply a risk to health, although socio-economic factors are also taken into account when the Standard is derived. The Occupational Exposure Standard (OES) is set at a level at which there is currently no indication of a risk to health. Occupational exposure limits are set on the recommendation of the Advisory Committee on Toxic substances (ACTS) with the toxicological, epidemiological and other available data assessed by the Working Group on the assessment of Toxic Chemicals (WATCH). The committees must decide which type of limit is appropriate for each chemical and the actual exposure limit concentration (HSE 1993, 1995) . Both the OES and the MEL can be expressed over both long and short term exposure. Long term exposures are normally expressed over an 8 hour Time Weighted Average (8h TWA), to control effects caused from prolonged or accumulated exposure. Short Term Exposure Limits are normally expressed as a 15 minute reference period, and are designed to prevent effects caused by brief exposures. The short term exposure limits are normally three times higher than the corresponding long term values, although this is dependent upon the nature of toxicity.

For an OES to be set, a chemical must meet all of the following criteria:

i) Scientific evidence is available to identify the concentration, averaged over a reference period, at which there is no indication that the substance is likely to be injurious to employees following daily exposures.

ii) Exposures to higher concentrations than the OES are unlikely to produce serious effects on health within the period of time it might reasonably be expected to take to identify excessive exposure and remedy its cause. Effects on health include sensory and other effects such as slowing of reflexes.

iii) There is reasonable evidence to indicate that compliance with the OES is reasonably practicable.

For a substance to be assigned an MEL it must meet one of the following criteria:

i) Exposure to the substance has, or is likely to have, serious health implications. The available evidence does not satisfy either Criteria 1 or 2 listed above.

ii) Socio-economic factors indicate that although the substance meets Criteria 1 and 2 for an OES, a numerically higher value is necessary if the controls associated with certain uses are to be regarded as reasonably practicable.

### C2.2.2 Procedure

When setting an OES the No Observed Adverse Effect Level (NOAEL) is determined. Ideally the NOAEL refers to humans exposed to the chemical via inhalation, although human data from other exposure routes or animal data are considered if human pulmonary data are not available. Both extrapolation factors and confidence limits are applied to the NOAEL in order to derive the OES. Scientific judgement is applied during all stages of the process.

The MEL is the maximum concentration of an airborne substance (averaged over a reference period) to which employees may be exposed by inhalation, under any circumstances. For an MEL to be assigned, there should be serious implications for the health of workers exposed to the substance. Serious health implications include both the risk of serious health effects to a small population of workers and the risk of relatively minor health effects to a large population. MELs are assigned to carcinogens and other substances for which no threshold can be identified, and for which there is no doubt about the seriousness of the effects of exposure.

In some instances there is a component of risk acceptability in the expression of the Standard with regard to specific exposure scenarios. For example, the *n*-hexane Standard was reduced from 100 to 20 ppm in air on the basis of changed perception of the importance of intermittent as opposed to continuous exposure to the solvent. The toxicological endpoints and the NOAELs remained the same but different interpretation was put on the available information.

### C2.2.3 Worked examples

**Benzene**

The hazards of benzene were identified from data on humans (HSE 1993). Exposure to benzene results in disorders of the blood-forming tissues including anaemia and leukaemia. No adverse effects on workers' health have been reported following an 8 hour Time Weighted Average (8h TWA) exposure to 25 to 30 ppm. Chromosomal damage has been reported in workers exposed to 5 to 10 ppm, but the health significance of these effects is unclear. Due to the carcinogenic nature of benzene, there is apparently no safe threshold for exposure, and so the Occupational Standard for Benzene was set as a Maximum Exposure Limit (MEL). The MEL was set at 5 ppm (16 mg $m^{-3}$) for an 8h TWA. A specific short term MEL was considered unnecessary. The MEL derived was reported to be achievable by industry.

The MEL for benzene was set below the NOAEL for humans. However the level has been shown to cause an effect (chromosomal damage) in some exposed workers, although the significance of this effect on health is unclear. This suggests that there is some degree of acceptable risk.

**Magnesium oxide**

The hazards of magnesium oxide were identified from data on humans (HSE 1993). Slight irritation of the eyes and nasal passages was reported in workers exposed to concentrations of magnesium oxide dust of 400 mg $m^{-3}$. However magnesium oxide fume (solid particles formed from condensation of magnesium vapour) is more harmful, with symptoms characteristic of metal fume fever (dry throat, headache, catarrh, fever and increased white blood cell count), reported in workers exposed to acute exposures ranging from 4 to 29 mg $m^{-3}$. The effects were reported to be threshold based, and so an Occupational Exposure Standard (OES) was set. OES values of 10 and 5 mg $m^{-3}$ were calculated for total inhalable dust and respirable dust/fume, respectively. The short term OES was set at 10 $mg/m^3$ (10 minute reference period)[1] for respirable dust and fume. It was decided that the normal guideline of having the short term exposure limit of three times the 8w TWA, was not stringent enough to protect against metal fume fevers due to intermittent exposures.

The OES Standards derived for magnesium oxide, therefore, take into account the hazards from the different forms. The separate Standards also take into account analytical methodologies to determine the total inhalable dust and respirable dust (fume) fractions.

## C2.3 Case Study 3: EU Air Quality Directives

### C2.3.1 Background

The existing separate EU Air Quality Directives are currently being revised to form a single Directive. The aim of the new Directive is to avoid, prevent or reduce the harmful effects of pollutants on human health and/or the environment as a whole, within the European Community. The Directive aims to take an integrated approach to protect air water and soil. It also aims to prevent activities in one Member State from affecting the environment of another Member State.

The EU Ambient Air Quality Directive aims to set limit values and alert thresholds (where appropriate) for 13 pollutants:

1. Sulphur dioxide
2. Nitrogen dioxide
3. Fine particulate matter including soot
4. Suspended particulate matter
5. Lead
6. Ozone
7. Benzene
8. Polyaromatic hydrocarbons
9. Carbon monoxide

[1] As of 1994, short term exposure limits were expressed with 15 minute reference periods, although this does not affect the value given for magnesium oxide.

10. Cadmium
11. Arsenic
12. Nickel
13. Mercury

The existing EU Air Quality Directives cover sulphur dioxide, nitrogen dioxide, fine particular matter, suspended particulate matter, lead and ozone. Limit values and alert thresholds, where appropriate, are to be proposed by the end of 1996 for pollutants 1 to 5 listed above.

The limit value for ozone is to be achieved in accordance with Article 8 of Council Directive 92/72/EEC for ozone. The UK has suggested that it may be necessary to fix a guide value for ozone and other secondary transfrontier pollutants such as photochemical particles.

Limit values, and alert thresholds are to be proposed as soon as possible, and no later than the end of 1999, for benzene, polyaromatic hydrocarbons, carbon monoxide, cadmium, arsenic, nickel and mercury.

Pollutants were selected for inclusion in the Directive with reference to the following guidelines (European Union 1995):

i) Possibility, severity and frequency of effects;. with regard to human health and the environment as a whole, the irreversible effects must be of special concern.

ii) Ubiquity and high concentration of the pollutant in the atmosphere.

iii) Environmental transformations or metabolic alterations which may produce chemicals which are more toxic than the parent compound.

iv) Persistence in the environment, especially chemicals which are not biodegraded and can accumulate in humans, the environment or food chains.

v) Impact of the pollutant with reference to both the size of the exposed population, living resources or ecosystems, and the existence of particularly sensitive targets in the zone concerned.

vi) Risk assessment methods may also be used. The pertinent danger criteria established under Directive 67/548/EEC and its successive adaptations shall be taken into account for the selection.

vii) Analysis of the situation. This includes analysis of those factors responsible for the excess (transport including cross-border transport, formation) and details of possible measures for improvement of air quality.

viii) Details of those measures/projects which existed prior to implementation of the Directive (local/regional/national/international).

ix) Details of those measures/projects adopted with a view to reducing pollution following implementation of the Directive.

x) Details of measures/projects planned/researched for the long term.

xi) List of publications, documents, work etc used to supplement the information requested.

The factors to be taken into account when setting limit values and alert thresholds include:

- Degree of exposure of sectors of the population, particularly sensitive sub-groups;
- Climatic conditions;
- Sensitivity of flora and fauna and their habitats;
- Historic heritage exposed to pollutants;
- Economic and technical feasibility;
- Long range transmission of pollutants and secondary pollutants, including ozone.

The Directive covers ambient air which is defined as "outdoor air in the troposphere, excluding work places and indoors". The limit values should be attained within a specified timescale, and once attained, should not be exceeded. The values are set according to scientific knowledge, with the aim of avoiding, preventing or reducing harmful effects on human health and/or the environment as a whole and have an associated "margin of tolerance". The target values are levels which have been set to avoid long term effects on human health and/or the environment. They should also be attained over a given period. The Alert threshold identifies the concentration above in which there is a risk to human health from acute exposures. When this threshold is exceeded, Member States must immediately take the steps specified in the Directive (e.g. inform the public by means of radio, television and the press)

Member States must draw up a list of zones and agglomerations in which pollutant levels exceed limit values plus the margin of tolerance. Measures should be taken to ensure that limit values are attained within a specified time.

Member States must also designate a competent body to ensure that the Directive is implemented. The designated body assesses the ambient air quality and approves measuring devices and assessment methods, ensuring accuracy of measurement, and co-ordination of Community-wide quality assurance programs within their state.

Member States can take more stringent measures than those laid down in the Directive, although they must inform the EU. Similarly, thresholds can be set for pollutants not listed in the Directive. Once the EU has been informed of such additional threshold values, it will examine the need for Community-wide implementation.

### C2.3.2 Procedure

The actual methodology used to derive these Standards has not been reported. The level of acceptable risk implicit in the derivation of these Standards is not explicitly stated and there is no specified risk assessment procedure. Presumably since these Standards refer to human health they seek to establish a level where there is no acceptable risk to humans. The use of these Standards to protect historic buildings is similarly unlikely to have any specified level of acceptable risk.

### C2.3.3 Worked examples

Detailed Information was not available on the derivation of the existing EU Standards for air.

## C2.4 Case Study 4: World Health Organisation (WHO) Air Quality Guidelines

### C2.4.1 Background

Air Quality Guidelines have been set for 27 chemicals by the European office of The World Health Organisation (WHO 1987). The guideline values are established by determining the concentrations which do not pose any hazard to the human population, and then the concentration which gives an acceptable risk is determined. WHO acknowledges that the risks are not the same for every member of the population and the risk management process includes identification of sub-populations which are more sensitive to the effects of the chemical. In addition, WHO derives Guidelines for some chemicals that aim to protect vegetation in terrestrial ecosystems exposed to pollutants as a result of atmospheric deposition.

### C2.4.2 Procedure

<u>Non-carcinogenic chemicals</u>

For compounds which are not defined as carcinogenic (data on carcinogenicity are lacking or insufficient), the LOAEL and/or the NOAEL is established for humans, animals and plants. The NOAEL in humans is frequently used. Protection factors are applied to the data as an indication of the confidence in the data. For example, protection factors are used in extrapolating laboratory animal data to human effects. The term protection factor is used instead of safety factor, as safety implies free from all risk.

Data on effects are ranked into three categories:

1. Observations are single findings which have not been verified by other groups. The lack of verification makes it difficult to base guideline values on the data.

The data can be used to indicate the need for further research and may be considered in evaluation of the margin of protection.

2. The LOAEL is represented by data which are supported by other scientific information. When the results are in the direction of pathological change there is a higher degree of health concern. Scientific judgement of all health information available is applied to determine how effects in this category can be used to determine the chemical concentration likely to pose an excessive risk.

3. A substantial change in the direction of pathological effects. These findings have a major influence on guideline considerations.

Scientific judgement is also applied to delineate concentration-exposure time interrelationships. Effects of some chemicals may be evident following short term exposures to high concentrations, whereas other chemicals exert effects following long term exposure to low concentrations. Expert judgement is applied to derive an appropriate reference period for each chemical.

The guidelines aim to protect human health, although they may also protect against indirect effects on health such as annoyance caused by malodorous properties. Odour threshold levels for such chemicals are used as a basis for separate guidelines.

## Carcinogenic chemicals

The guideline values for chemicals defined as carcinogenic are derived in a different way. Chemicals classified by the International Agency for Research on Cancer (IARC) as Group 1 or 2A have guidelines formulated with a risk estimate. Chemicals in Group 2B contain guidelines identifying the carcinogenicity in animals and cite risk estimates in the health risk evaluation section of the scientific background information. Risk estimates based only on animal data are not incorporated in the guideline recommendations due to the uncertainties implicit in extrapolation to humans. The guideline values for these pollutants are derived from non-carcinogenic endpoints.

WHO carry out quantitative risk assessments of carcinogenicity potential. Data are taken from high exposure studies such as on laboratory mammals or occupational exposure, and applied to the general population. The method of risk extrapolation is based on current understanding of carcinogenesis, although it is generally non-threshold based. Incremental risk estimates are defined as the additional lifetime cancer risk occurring in a hypothetical population, in which all individuals are exposed continuously from birth, to a concentration of 1 $\mu g\ m^{-3}$. The use of risk estimates allows the carcinogenic potency of different chemicals to be compared and it avoids any reference to the acceptability of risk, which is normally decided upon by the national authorities within the risk management framework.

The quantitative assessment of risk for chemicals defined as carcinogens, involves four stages (WHO 1987):

1. **Selection of studies:** A reliable human study is identified in which the exposure can be estimated and for which there is a statistically significance increase in

cancer incidence. If there are reliable data from more than one study, then all the data are examined and evaluated by expert scientists.

2. **Calculate the relative risk:** The relative risk, as a measure of response is calculated. The 95% confidence limits are also calculated and evaluated.

3. **Extrapolate towards zero dose:** The relative risk is fed in to a model to achieve this. The choice of extrapolation model depends on current understanding of carcinogenesis. No single mathematical procedure is used in the extrapolation. The models used tend to be based on linear, non-threshold assumptions rather than models which assume a safe threshold.

4. **Application to a general (hypothetical) population:** The model produces a value for the unit lifetime risk.

The guidelines for the protection of human health therefore have the level of risk explicitly reported for carcinogenic endpoints. For non-carcinogenic end-points, the guidelines provide thresholds below which adverse effects are unlikely to occur.

In addition to Guidelines for human health, WHO has also set some guidelines to protect vegetation in ecosystems. These values are derived in a comparable manner to the air quality guidelines. Guidelines are currently available for nitrogen, ozone and other photochemical oxidants, and sulphur oxides. The aim of the guidelines is to protect the functions of vegetation in the ecosystem. The functions of vegetation listed by WHO are producer, economic resource and gene reservoir (WHO 1987). The degree of risk assessment in the guideline values for the ecosystem is not explicitly stated.

### C2.4.3 Worked examples

**Sulphur Dioxide**

PROTECTION OF HUMAN HEALTH:

WHO has reported that the lowest concentration of sulphur dioxide to affect human health is 1000 $\mu g\ m^{-3}$ following a 10 minute exposure. This value was obtained from experiments in humans, although asthmatics, a sub-group of the population which are more sensitive to the effects of sulphur dioxide were not included. A safety factor of two was applied to the data to give a guideline value of 500 $\mu g/m^3$ for a 10 minute exposure. A 1 hour maximum value which conforms with the guideline value was calculated to be 350 $\mu g/m^3$.

PROTECTION OF VEGETATION:

The lowest concentrations of sulphur dioxide reported to be toxic to macrophytes are 43 and 55 $\mu g\ m^{-3}$ for ryegrass and tobacco and cucumber, following 173 and 28 days exposure, respectively. Sulphur dioxide has also been reported as toxic to trees at concentrations ranging from 20 to 40 $\mu g\ m^{-3}$. The guideline value for the protection of vegetation against the adverse effects of sulphur dioxide has been set as 30 $\mu g\ m^{-3}$ as an annual average, and 100 $\mu g\ m^{-3}$ as a 24 hour average. WHO acknowledge that the

guideline value may not be stringent enough to protect vegetation in extreme environmental conditions or in the presence of other ubiquitous pollutants.

This example demonstrates how separate guideline values can be set to protect human health and the environment. The guideline values calculated were based on different toxicological endpoints, and therefore have different exposure times.

### C2.4.3 Worked examples

**Benzene**

Benzene is a carcinogen, and therefore has no apparent safe exposure level. The risk of developing cancer following exposure to benzene was calculated using data from occupational exposures. Workers exposed to benzene during rubber plant manufacture were studied during a 25 year follow-up period. The number of mortalities from leukaemia was calculated to be 5.6 times higher than the national average. Workers were likely to have been exposed to benzene concentrations between 30 and 300 mg $m^{-3}$ for an average of 8.5 years. The average lifetime daily exposure was calculated as follows:

300 mg $m^{-3}$ x 8/24 hours x 240/365 days x 8.5/70 years = 8 mg $m^{-3}$

The unit risk associated with a lifetime exposure to 1 µg $m^{-3}$ of benzene was calculated to be:

National mortality rate (relative risk - 1)/average lifetime daily exposure

0.007 (5.6 - 1)/8000 = 4 x $10^{-6}$.

# C3 OTHER PROCEDURES

## C3.1 United Nations Economic Commission for Europe Convention on Long Range Transboundary Air Pollution (UNECE Protocol) - Critical Loads

### C3.1.1 Background

The UN Economic Commission for Europe comprises all the countries in Europe and North America. The Convention on Long Range Transboundary Air Pollution was adopted in Geneva in 1979. The Convention arose mainly from concerns from Scandinavian countries on the long range transport of pollutants such as sulphur dioxide and nitrogen oxides, although other pollutants such as nitrogen and chlorine compounds, polycyclic aromatic hydrocarbons, heavy metals and particulate matter are now also included. The Convention states that countries should "endeavour to limit and, as far as possible, gradually reduce and prevent air pollution, including long range transboundary air pollution" (NCSA 1994).

All Parties to the Convention were invited to send experts to workshops which evaluated the concept of Critical Loads/Levels and provided reliable figures. The specific aims of these workshops were to define:

1. Critical Levels for direct effects of air pollutants on forests, crops, materials and natural vegetation;

2. Critical loads for sulphur and nitrogen compounds.

A critical load can de defined as "the maximum deposition of a given compound which will not cause long term harmful effects on ecosystem structure and function, according to present knowledge (Institute of Terrestrial Ecology, 1993). In simpler terms, this means that it is a threshold deposition which can be tolerated by the ecosystem without damage. Critical loads underpin integrated pollution control since the receptors studied include both aquatic and terrestrial environmental compartments including the biota they support.

The critical load concept is currently dominating air pollution legislation in Europe. The critical loads approach has been used for depositions of sulphur and nitrogen within the framework of the UNECE under the Convention on Long Range Transboundary air pollution.

### C3.1.2 Procedure

Detailed information on the derivation of Critical Loads/Levels was not available. However, the derivation of Critical Loads for pollution abatement occurs in nine stages (Bull 1992):

1. Select pollutant
2. Select appropriate sensitive receptor
3. Determine critical chemical limit
4. Select method
5. Regionalize areas
6. Collect necessary data
7. Calculate critical load
8. Use deposition data to assess if critical loads are exceeded
9. Apply critical load values to emission-deposition models

Critical loads are measures of receptor sensitivity and are often derived from physico-chemical properties since biological measures are difficult to define. Critical Loads are expressed as deposition rates from the atmosphere. Critical Levels can only be derived from empirical data such as laboratory experiments and observation of effects in the field. Critical Levels are expressed as concentrations in the environmental compartment associated with specific biological effects; the NOEC depends on the biological endpoints monitored. Whilst it is possible to calculate the Critical Load associated with particular Critical Levels, it is not possible to derive Critical Levels from Critical Loads.

The Critical Loads approach is iterative; provisional Critical Loads are set as temporary values and the concept includes revisiting the Standard at regular intervals to monitor what improvements have been achieved. Industry has the opportunity to conduct research to assess the stringency of the existing value. Guidance values have the advantage in that they can be revised more readily than Standards which are enshrined in legislation.

### C3.1.3 Worked example

Since detailed information is not available concerning the derivation of Critical Loads, it is not possible to give a worked example. However, Table C1 lists the current Critical Loads for nitrogen and the basis for their derivation.

**Table C1 Critical loads for nitrogen (as of December 1995)**

| Receptor | Indication | Critical load kg N $ha^{-1}$ $yr^{-1}$ |
|---|---|---|
| **Trees and different forest ecosystems** | | |
| Coniferous trees (acidic) | Nutrient imbalance (low nitrification rate) | 10 to 15 |
| Coniferous trees (acidic) | Nutrient imbalance (moderate to high nitrification rate) | 20 to 30 |
| Deciduous trees | Nutrient imbalance; increased shoot/root | 15 to 20 |
| Acidic coniferous forest | Changes in ground flora and mycorrhizas; increased leaching | 7 to 20 |
| Acidic deciduous forest | Changes in ground flora and mycorrhizas | 10 to 20 |
| Calcareous forests | Changes in ground flora | 15 to 20 |
| Acidic forest | Changes in ground flora and leaching | 7 to 15 |
| Many forests in humid climates (oceanic) | Decline in lichens and free-living algae | 5 to 10 |

| Receptor | Indication | Critical load kg N $ha^{-1}$ $yr^{-1}$ |
|---|---|---|
| **Grasslands with high conservation importance** | | |
| Calcareous species-rich grasslands | Increased mineralisation and nitrogen accumulation; leaching and risk of vegetation change | 15 to 35 |
| Neutral-acid species-rich grasslands | Increase tall grass, change in diversity | 20 to 30 |
| Montane-subalpine grassland | Increase tall graminolds, change in diversity | 10 to 15 |
| **Heathland ecosystems** | | |
| Lowland dry heaths | Transition heather to grass; functional change (litter production; flowering; nitrogen accumulation) | 15 to 20 |
| Lowland wet heaths | Transition heather to grass | 17 to 22 |
| Species-rich heaths acidic grasslands | Decline in sensitive species | 10 to 15 |
| Upland Calluna heaths | Decline in heather dominance, mosses and lichens; nitrogen accumulation | 15 to 20 |
| Arctic and alpine heaths | Decline in lichens, mosses and evergreen dwarf shrubs | 5 to 15 |
| **Wetlands** | | |
| Mesotrophic fens | Increase in tall graminoids, decline in diversity | 20 to 35 |
| Ombrotrophic bogs | Decrease in typical mosses, increase in tall graminoids, Nitrogen accumulation | 5 to 15 |
| Shallow soft-water bodies | Decline in isoetid species | 5 to 10 |

## C3.2 ITE Blueprint for the protection of the environment

While this methodology is not used for setting specific standards, it is worth considering as a means of assessing risk of effects on terrestrial organisms following exposure to atmospheric emissions of chemicals.

The environmental blueprint was developed to assess the risk of atmospheric emissions of chemicals to British species of birds and mammals (Dobson *et al* 1995). The methodology used is analogous to that of the critical loads approach for atmospheric pollutants, with birds and mammals defined as receptors. The risks to wildlife exposed to a chemical emission are calculated in the following manner:

i) Dietary LC50 values (mg $kg^{-1}$ diet) from published five day dietary toxicity tests are used to calculate an LD50 (mg $kg^{-1}$ body weight $day^{-1}$) using known food consumption data for the test species. The data on test species can be used to calculate LC50s (mg $kg^{-1}$ dry weight diet) for all bird species, based on published body weight and food consumption data. This gives an indication of the potentially most-sensitive species and can be compared with published data, if available, for more than one species.

ii) The land classes in the area of the industrial plant are identified, with subsequent identification of the species of birds and mammals associated with these land classes (Howe *et al* 1994 and 1995). Species with varying body weight and food type are selected.

The exposure of a species to a chemical in various food types is established from previously published studies and the risk factors for selected species and food types are established. Risk factors can be expressed as either the ratio between toxicity and exposure, or as the percentage of daily food intake required for toxicity. The ratio is ideally expressed as the NOEC:exposure concentration, with values less than 1 being indicative of risk. However, for birds the LC50 value may be used since the NOEC is often unavailable, and therefore values up to 3 can indicate potential problems. For mammals, toxicity is normally expressed as the LOEC with regard to liver damage. Sub-lethal effects reported in the laboratory are likely to be lethal to organisms under field conditions. Problems may be encountered if the risk, expressed as percentage of daily food intake is lower than 100%.

The blueprint does not claim to give a totally accurate picture of what effects chemicals will have on all species. It does, however, allow a ranking of species for likely effects of exposure in the field. For any given chemical emission, the species associated with local habitats can be identified and a preliminary risk assessment can be performed using expected exposure concentrations and the estimated sensitivity of the species. This gives an estimate of whether species with particular food preference, body weight, geographical distribution or habitats are likely to be adversely affected. The risk assessments give an initial indication of risk. Field studies and monitoring can then be performed, if problems are highlighted.

## C3.3 Integrated Risk Information System (IRIS) Database

Health assessment information on a chemical is only included in the IRIS database following a comprehensive review of chronic toxicity data by scientists from several programme offices within the US EPA. The hazards (non-carcinogenic endpoints) are reviewed and a reference concentration for chronic inhalation exposure is established. The carcinogenicity assessment for lifetime exposure is calculated in a similar manner to the WHO assessments. The carcinogenicity classification is established using a weight of evidence judgement to determine whether the chemical is a human carcinogen. Quantitative estimates are made of the risk from inhalation exposure and are presented in three ways:

i) The slope factor is the result of application of a low dose extrapolation procedure and is presented as the risk (mg $kg^{-1}$) per day

ii) The unit risk is the quantitative estimate in terms of risk per $\mu g\ m^{-3}$ air breathed.

iii) The third presentation of risk is the air concentrations which give cancer risks of 1 in 10 000, 1 in 100 000 and 1 in 1 000 000.

This Standard is aimed at the protection of human health. The risk associated with the Standard is explicitly quantified in the three levels of increased risk of carcinogenicity as listed above.

# APPENDIX D STATUTORY ENVIRONMENTAL STANDARDS

This appendix summarises the statutory environmental standards for air, water and land (sewage sludge application) that are pertinent to HMIP.

## D1 STANDARDS FOR WATER

**Table D1 Environmental Quality Standards for List I (76/464/EEC) Substances[1]**

| Parameter | Environmental quality standard (µg $l^{-1}$) | | | Standstill Provision |
|---|---|---|---|---|
| | Inland | Estuarine | Marine | |
| Mercury | 1.0 TAA | 0.5 DAA | 0.3 DAA | Yes |
| Cadmium | 5.0 TAA | 5.0 DAA | 2.5 DAA | Yes |
| Hexachlorocyclohexane | 0.1 TAA | 0.02 TAA | 0.02 TAA | Yes |
| Carbon tetrachloride | 12.0 TAA | 12.0 TAA | 12.0 TAA | No |
| Total-DDT | 0.025 TAA | 0.025 TAA | 0.025 TAA | Yes |
| Para-DDT | 0.01 TAA | 0.01 TAA | 0.01 TAA | Yes |
| Pentachlorophenol | 2.0 TAA | 2.0 TAA | 2.0 TAA | Yes |
| Total drins | 0.03 TAA | 0.03 TAA | 0.03 TAA | Yes |
| Aldrin | 0.01 TAA | 0.01 TAA | 0.01 TAA | Yes |
| Dieldrin | 0.01 TAA | 0.01 TAA | 0.01 TAA | Yes |
| Endrin | 0.005 TAA | 0.005 TAA | 0.005 TAA | Yes |
| Isodrin | 0.005 TAA | 0.005 TAA | 0.005 TAA | Yes |
| Hexachlorobenzene | 0.03 TAA | 0.03 TAA | 0.03 TAA | Yes |
| Hexachlorobutadiene | 0.1 TAA | 0.1 TAA | 0.1 TAA | Yes |
| Chloroform | 12.0 TAA | 12.0 TAA | 12.0 TAA | No |

| Parameter | Environmental quality standard (µg $l^{-1}$) | | | Standstill Provision |
|---|---|---|---|---|
| | Inland | Estuarine | Marine | |
| 1,2-Dichloroethane | 10.0 TAA | 10.0 TAA | 10.0 TAA | No |
| Perchloroethylene | 10.0 TAA | 10.0 TAA | 10.0 TAA | No |
| Trichlorobenzene | 0.4 TAA | 0.4 TAA | 0.4 TAA | Yes |
| Trichloroethylene | 10.0 TAA | 10.0 TAA | 10.0 TAA | No |

**Notes:**

[1] From Department of the Environment Circular 7/89: Water and the Environment - The Implementation of European Community Directive on Pollution caused by certain Dangerous Substances Discharged into the Aquatic Environment

T Total concentration
D Dissolved concentration
AA Annual average

**Table D2 National Environmental Quality Standards for List II (76/464/EEC) Substances[1]**

| | Metal ($\mu g\ l^{-1}$) | | | | | |
|---|---|---|---|---|---|---|
| **Water Use** | **Lead** | **Chromium** | **Zinc** | **Copper** | **Nickel** | **Arsenic** |
| 1. Abstraction to potable supply for treatment requirements: | | | | | | |
| A1 | na | 50 PT | 50 PT | 3000 PT | 20 PT | 50 PT |
| A2 | na | 75 MT | 75 MT | 5000 PT | 50 PT | 50 PT |
| | | | | | | |
| 2. Protection of Sensitive Aquatic Life, for water hardness: | | | | | | |
| 0-50 ($mg\ l^{-1}$ of $CaCO_3$) | 4 AD | 5 AD | 8 AT(30P) | 1 AD(5P) | 50 AD | 50 AD |
| 50-100 | 10 AD | 10 AD | 50 AT(200P) | 6 AD(22P) | 100 AD | 50 AD |
| 100-150 | 10 AD | 20 AD | 75 AT(300P) | 10 AD(40P) | 150 AD | 50 AD |
| 150-200 | 20 AD | 20 AD | 75 AT(300P) | 10 AD(40P) | 150 AD | 50 AD |

| | Metal ($\mu g\ l^{-1}$) | | | | | |
|---|---|---|---|---|---|---|
| **Water Use** | **Lead** | **Chromium** | **Zinc** | **Copper** | **Nickel** | **Arsenic** |
| 200-250 | 20 AD | 50 AD | 75 AT(300P) | 10 AD(40P) | 200 AD | 50 AD |
| 250 and above | 20 AD | 50 AD | 125 AT(500P) | 28 AD(112P) | 200 AD | 50 AD |
| | | | | | | |
| 3. Protection of other Aquatic Life, for water hardness: | | | | | | |
| 0-50 ($mg\ l^{-1}$ of $CaCO_3$) | 50 AD | 150 AD | 75 AT(300P) | 1 AD(5P) | 50 AD | 50 AD |
| 50-100 | 125 AD | 175 AD | 175 AT(700P) | 6 AD(22P) | 100 AD | 50 AD |
| 100-150 | 125 AD | 200 AD | 250 AT(1000P) | 10 AD(40P) | 150 AD | 50 AD |
| 150-200 | 250 AD | 200 AD | 250 AT(1000P) | 10 AD(40P) | 150 AD | 50 AD |
| 200-250 | 250 AD | 250 AD | 250 AT(1000P) | 10 AD(40P) | 200 AD | 50 AD |
| 250 and above | 250 AD | 250 AD | 500 AT(2000P) | 28 AD(112P) | 200 AD | 50 AD |
| | | | | | | |
| 4. Protection of salt water life | 25 AD | 15 AD | 40 AD | 5 AD | 30 AD | 25 AD |

**Table D3 National Environmental Quality Standards for List II Substances[1]**

| | Metal ($\mu g\ l^{-1}$) | | | | | |
|---|---|---|---|---|---|---|
| **Water Use** | **Boron** | **Iron** | **pH** | **Vanadium** | **Tributyltin** | **Triphenyltin** |
| 1. Abstraction for potable supply, treatment requirements: | | | | | | |
| A1 | 1000 PT | 1300 PD | 6.5-8.5P | | 0.02 MT | 0.09 MT |
| A2 | 1000 PT | 2000 PD | 5.5-9.0P | | 0.02 MT | 0.09 MT |
| | | | | | | |
| 2. Protection of sensitive aquatic life: | | | | | | |
| All Hardnesses | 2000 AT | 1000 AD | 6.0-9.0P | | 0.02 MT | 0.02 MT |
| 0-200 (mg $l^{-1}$ of $CaCO_3$) | | | | 20 AT | | |
| 200 and above | | | | 60 AT | | |
| | | | | | | |
| 3. Protection of other aquatic life | | | | | | |
| All Hardnesses | 2000 AT | 1000 AD | 6.0-9.0P | | 0.02 MT | 0.02 MT |
| 0-200 (mg $l^{-1}$ of $CaCO_3$) | | | | 20 AT | | |
| 200 and above | | | | 60 AT | | |
| | | | | | | |
| 4. Protection of salt water life | 7000 AT | 1000 AD | 6.0-8.5P | 100 AT | 0.002 MT | 0.008 MT |

**Table D4 National Environmental Quality Standards for List II Substances[1]**

| | Mothproofing Agents (µg $l^{-1}$) | | | | |
|---|---|---|---|---|---|
| **Water Use** | **PCDs** | **Cyfluthrin** | **Sulcofuron** | **Flucofuron** | **Permethrin** |
| 1. Abstraction for Potable Supply: | | | | | |
| A1 | | 0.001 PT | | | 0.01 PT |
| A2 | | 0.001 PT | | | 0.01 PT |
| | | | | | |
| 2. Protection of Sensitive Aquatic Life | 0.05 PT | 0.001 PT | 25 PT | 1.0 PT | 0.01 PT |
| | | | | | |
| 3. Protection of Other Aquatic Life | 0.05 PT | 0.001 PT | 25 PT | 1.0 PT | 0.01 PT |
| | | | | | |
| 4. Protection of Salt Water Life | 0.05 PT | 0.001 PT | 25 PT | 1.0 PT | 0.01 PT |

Notes:

[1] From Department of the Environment Circular 7/89: Water and the Environment - The Implementation of European Community Directive on Pollution caused by certain Dangerous Substances Discharged into the Aquatic Environment

T Total concentration
D Dissolved concentration
A Annual average
P 95% of samples
M Maximum allowable concentration

# D2 STANDARDS FOR AIR

**Table D5 Limit values for Sulphur Dioxide and Suspended Particulates (as measured by the Black Smoke method)[1]**

| Reference Period | Limit Value for Sulphur Dioxide ($\mu g\ m^{-3}$) | Associated Value for Suspended Particulates ($\mu g\ m^{-3}$) |
|---|---|---|
| Year | 80 (median of daily mean values taken throughout the year) | > 40 (median of daily mean values taken throughout year) |
| | 120 (median of daily mean values taken throughout year) | < 40 (median of daily mean values taken throughout year |
| Winter (1 Oct to 31 March) | 130 (median of daily mean values taken throughout winter) | > 60 (median of daily mean values taken throughout winter) |
| | 180 (median of daily mean values taken throughout winter) | < 60 (median of daily mean values taken throughout winter) |
| Year (made up of units of measuring periods of 24 hours) | 250 (98 percentile of all daily mean values taken throughout the year) | > 150 (98 percentile of all daily mean values taken throughout the year) |
| | 350 (98 percentile of all daily mean values taken throughout the year) | < 150 (98 percentile of all daily mean values taken throughout the year |

**Table D6 Limit Values for Nitrogen Dioxide[2] and Lead[3]**

| Substance | Limit value (μg $m^{-3}$) |
|---|---|
| Nitrogen Dioxide | 200 (98th percentile calculated from the mean values per hour or per period of less than an hour recorded throughout the year) |
| Lead | 2 (as an annual mean concentration) |

**Table D7 Thresholds for Ozone Concentrations in the Air[4]**

| Target to be Protected | Threshold (μg $m^{-3}$) |
|---|---|
| Health Protection Threshold | 110 (mean value over 8 hours) |
| Vegetation Protection Threshold | 200 (mean value over one hour) |
| | 65 (mean value over 24 hours) |
| Population Information Threshold | 180 (mean value over one hour) |
| Population Warning Threshold | 360 (mean value over one hour) |

Notes:

1 Council Directive on Air Quality Limit Values for Sulphur Dioxide and Suspended Particulates (80/779/EEC)
2 Council Directive on Air Quality Standards for Nitrogen Dioxide (85/203/EEC)
3 Council Directive on a Limit Value for Lead in Air (82/884/EEC)
4 Council Directive on Air Pollution by Ozone (92/72/EEC).

# D3 STANDARDS FOR LAND

**Table D8 Limit Values for Metals in Sludge Applied to Agricultural Land[1]**

| Element | Kg per hectare per year | Limit of detection (mg $kg^{-1}$ of dry matter) |
|---|---|---|
| Zinc | 15 | 50 |
| Copper | 7.5 | 25 |
| Nickel | 3 | 10 |
| Cadmium | 0.15 | 1 |
| Lead | 15 | 25 |
| Mercury | 0.1 | 0.1 |

**Table D9 Limit Values for Metals in Soil to which Sewage Sludge is applied, expressed as mg $kg^{-1}$ of dry matter[1]**

| | pH | | | |
|---|---|---|---|---|
| **Element** | **5.0-5.5** | **5.5-6.0** | **6.0-7.0** | **>7.0** |
| Zinc | 200 | 250 | 300 | 450 |
| Copper | 80 | 100 | 135 | 200 |
| Nickel | 50 | 60 | 75 | 110 |
| | | | | |
| | **For pH 5.0 and above** | | | |
| Lead | 300 | | | |
| Cadmium | 3 | | | |
| Mercury | 1 | | | |

Notes:
[1] Sludge (Use in Agriculture) Regulations 1989